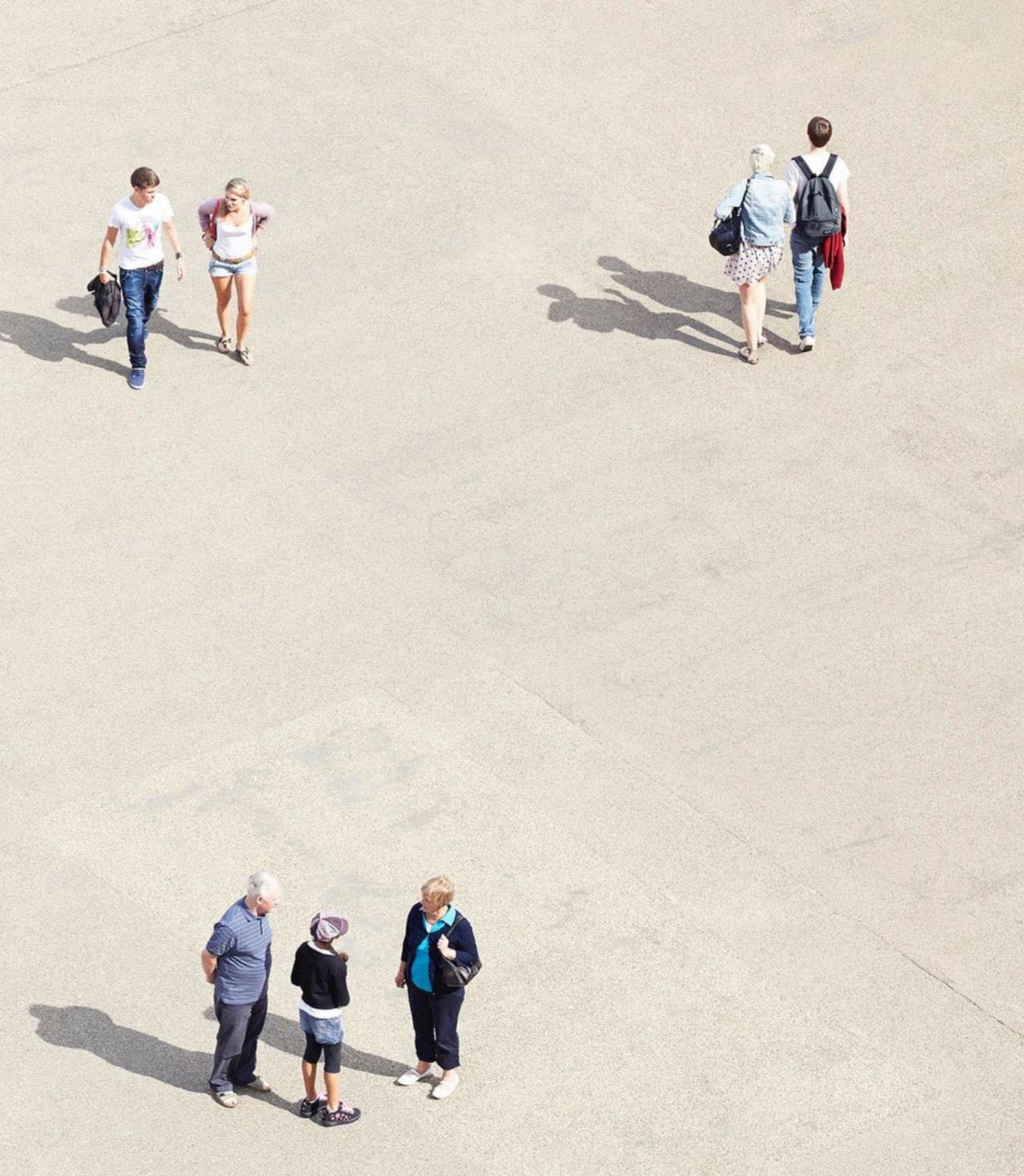


## Staying Ahead of an Evolving Pharmacy Landscape

Muji Iqbal, Pharm.D., Pharmacy Consultant

Mark Satre, West and South Region Pharmacy VP

June 26, 2024





### **Today's Discussion**

**Vertical Integration** and New Pharmacy Players

2

Managing GLP-1s



## 3

#### **Biosimilars and** Gene and Cell Therapy





# Vertical Integration and New Pharmacy Players



Proprietary and Confidential — Manufacturers Alliance Aon Pharmacy



## The Rapidly Evolving Pharmacy Landscape

GLP-1s Have Changed Everything

- Cardiovascular indication
- Overall utilizers up 43 percent
- Weight loss utilizers up 200+ percent
- Expanded access expected
- Oral (pills) expected in 2024

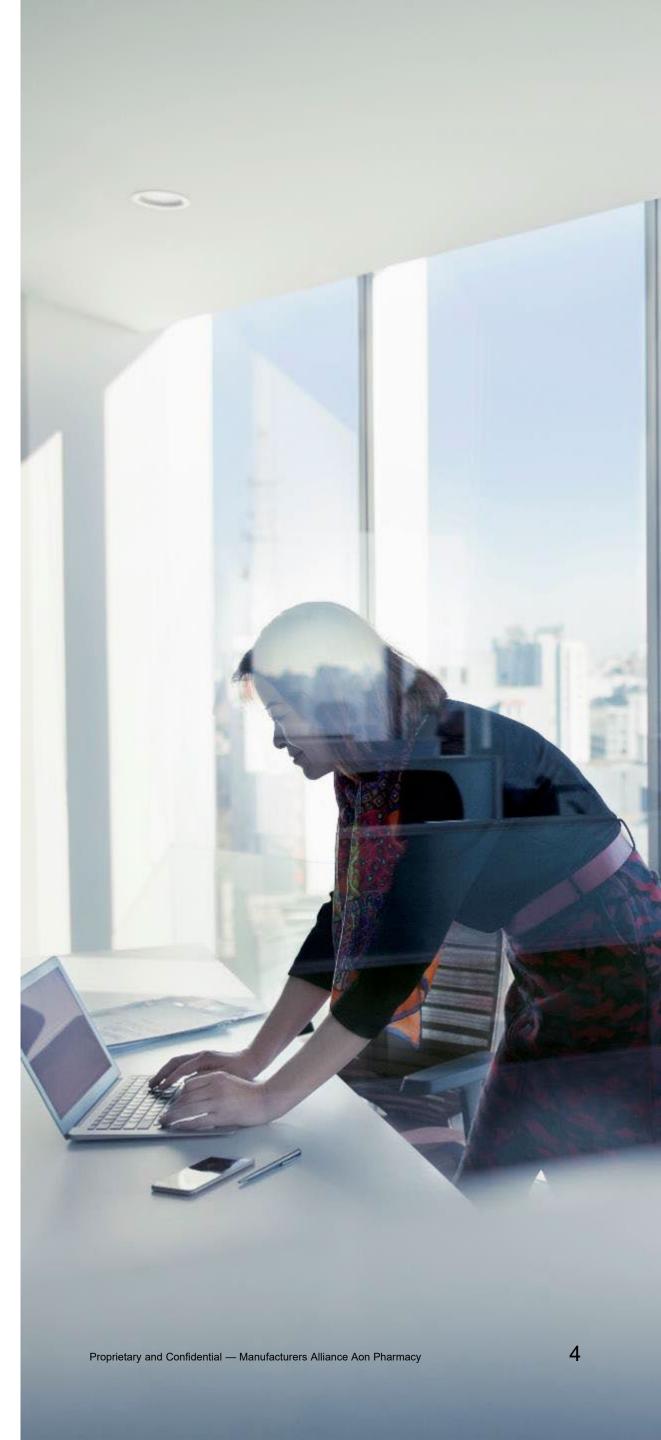
Drug Innovation and New Vendor Entrants

- Biosimilars
- Merging PBMs
- Gene and cell therapy pipeline
- Multi-million-dollar one-time therapies will hit in 2025
- Highest volume of drug approvals in five years



Forces Shaping the Future of Pharmacy

- Federal and state legislative efforts are at an all-time high
- Lawsuits involving key stakeholders
- Drug shortages
- Aging population
- Evolving distribution channels and care networks



### Vertical Integration and Carrier-Owned PBMs The Pharmacy Benefit Landscape is Complicated

Vertically integrated medical carriers pay nearly 70% of all commercial insurance claims, pharmacy and medical

### 80%

of all pharmacy claims in the U.S. are managed by the Big 3 PBMs

### 90%+

of all rebatable claims **flow through GPOs owned by the Big 3 PBMs** and their integrated medical carriers





### **Emerging and Trending PBM Themes**

**Clinical-First PBMs** are built upon the belief that traditional PBMs have incentives to increase utilization and to approve prior authorizations, especially where they own the mail-order and specialty pharmacies. These PBMs integrate clinicians into their call centers and require use of their clinical programs.



**Redefining the Prices by developing or applying different sources for pricing.** This includes PBMs, but also discount card programs and standalone pharmacies with unique dispensing models. For example, CapitalRx is a PBM that uses National Average Drug Acquisition Cost (NADAC) data for claims reimbursement.

Capital Rx - GoodRx C Cost Plus

**Transparency** in response to pressure from consumers, legislators and industry advocates to understand the mechanics of PBM profits. All PBMs claim to offer clients transparency. Know that there are different shades of transparency!





### **News-Making Pharmacy Announcements from Innovators, Outliers**





HEALTH AND SCIENCE

### Tyson Foods drops CVS for upstart pharmacy benefit manager, as industry upheaval over cost concerns spreads

PUBLISHED WED, JAN 24 2024-9:18 AM EST | UPDATED WED, JAN 24 2024-2:56 PM EST



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KEY POINTS

 Tyson Foods has switched from CVS' Caremark as its pharmacy benefit manager, in an effort to lower the amount it spends on providing drug benefits to its 140,000 employees





### **Pharmacy Legislation Headlines**

### In 2023, over 800 bills proposed across all 50 states. Intent include:

- PBM reform
- Decreasing patient cost
- Increasing access to medications
- Reducing high drug prices

#### The American Rescue Plan Act — AMP CAP

- Eliminated the current rebate cap drug manufacturers pay to Medicaid
- Impact to plans:
  - Up to 70 percent reduction in insulin drug prices
  - Significantly reduced rebates
  - PBM updated contract terms through reservation of rights

### Do not accept a PBM-initiated "Insulin Rebate Credit" contract amendment without talking to Aon.

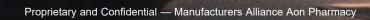






### Managing GLP-1s





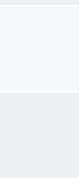


# Drop Your Answer in the Chat... What do These Three Percentages Represent?

224.1%	
193.2%	
223.0%	









# Drop Your Answer in the Chat... What do These Three Percentages Represent?

224.1%	The gross cost trend incr
193.2%	Weight loss utilizers tren
223.0%	Weight loss prescription



crease for weight loss drugs in CY 2023

nd increase in 2023

trend increase in 2023



# Drop Your Answer in the Chat... What do These Three Percentages Represent?

Jan – April 2024		
87.9%	224.1%	The gross cost trend incr
78.6%	193.2%	Weight loss utilizers trend
89.2%	223.0%	Weight loss prescription

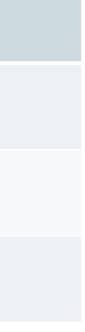


crease for weight loss drugs in CY 2023

nd increase in 2023

trend increase in 2023





### How are Clients Viewing Their Pharmacy Benefits Today? Concerns About GLP-1s Rank Third Behind Affordability and Specialty Drugs

#### What are the biggest challenges faced by your prescription drug plan today?

Increasing costs for specialty medications

Increasing utilization of specialty medications

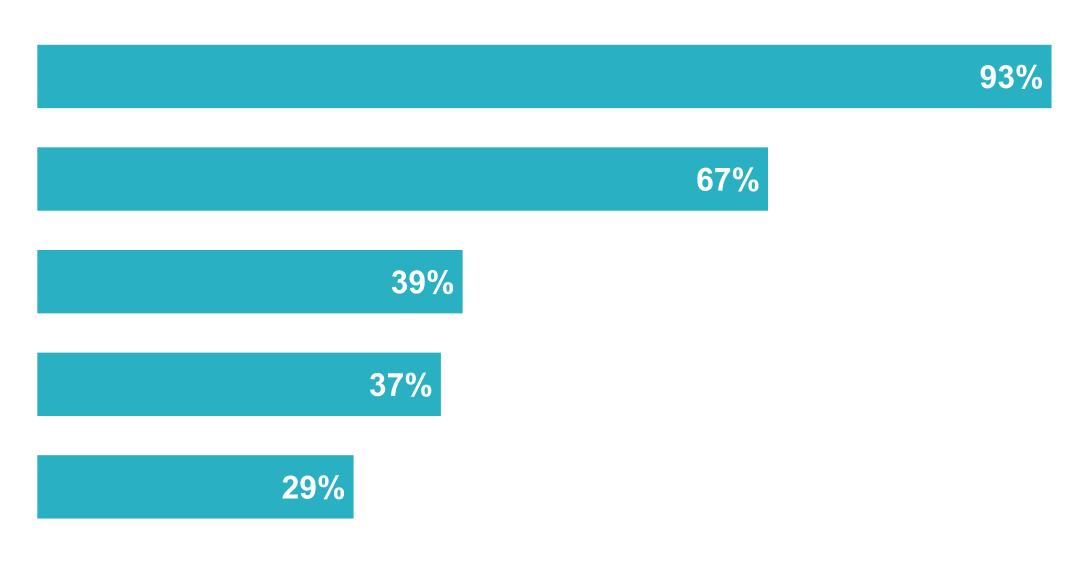
Member drug affordability

Increasing utilization/costs of GLP-1 medications for diabetes

Increasing utilization/costs of GLP-1 medications for obesity

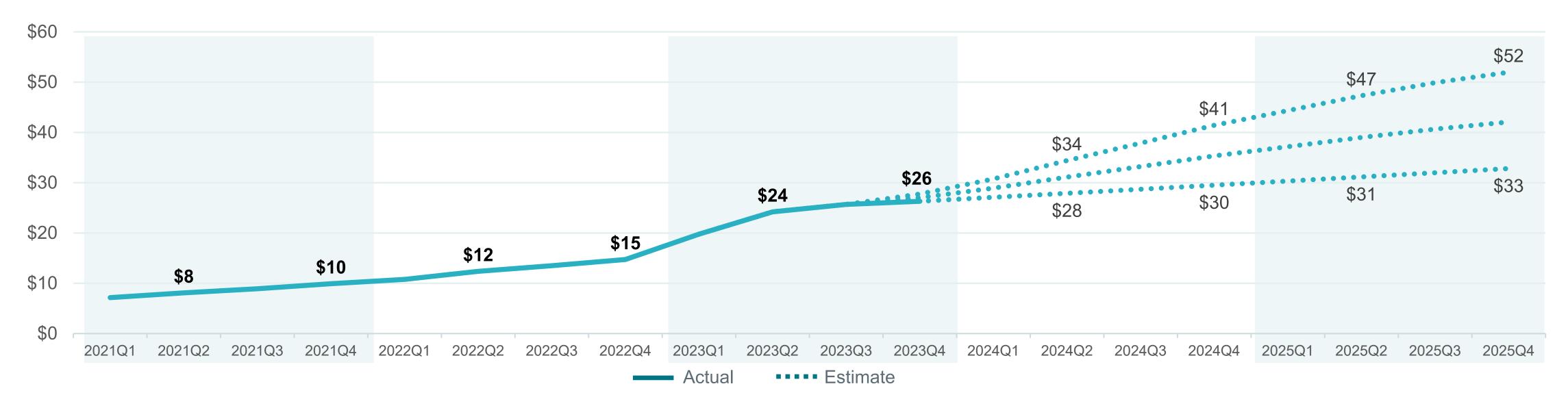
Aon Health Survey, Q4 2023, 433 respondents in large, middle and small sized firms.





### GLP-1 Future State — Anti-Obesity and Diabetes GLP-1 Coverage

#### Spring 2024 — GLP-1 Gross Cost PMPM Projection for Average Client



- Utilization increases slowed at the end of 2023.
- Current spend as of Q4 2023 for all GLP-1 medications is \$26 PMPM; mid-estimate projects increase to \$42 by end of 2025.
- Growth tailwinds include approvals for new indications (e.g., Wegovy approved for cardiovascular disease 3/8/2024) and release of oral formulations for obesity.
- Growth headwinds include supply issues, stricter PAs, requirements to enroll in lifestyle management programs and/or plan exclusions.

Notes: Data above reflects Aon client averages from PBM reporting. Data includes 482 clients and ~4.3M members. The projected 2024 – 2025 PY GLP-1 increase is preliminary and will be monitored and updated as more data emerges.





### **GLP-1s: The Latest Cost Driver in Obesity Care**

**46%** of large employers cover GLPs for weight loss while 92% of employers cover it for diabetes.

#### **Prevalence**

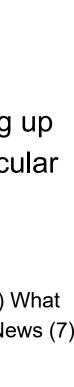
Many employers emergently stopped covering GLP-1s for weight loss all together as a stop gap measure to contain costs.

Average cost of an Anti-Obesity Medication (GLP-1) is ~\$1,350/month compared to insulin for diabetes at **\$35/month** for insulin.

Sources: (1) Obesity and Cancer Fact Sheet – NCI; (2) Direct medical costs of obesity in the United States and the most populous states - PubMed (nih.gov) (3) 10 Health Conditions & Diseases Linked To Obesity (webmd.com) (4) What Causes Type 2 Diabetes? Risk Factors, Lifestyle, and More (webmd.com) (5) Obesity and Osteoarthritis Fact Sheet - Obesity Action Coalition (6) Weighing the benefits of Ozempic and Wegovy in health plans | Employee Benefit News (7) Business Group on Health 2024 Large Employer Health Care Strategy Survey (8) https://www.hsph.harvard.edu/obesity-prevention-source/obesity-consequences/health-effects/



GLP-1s for weight loss is the **first innovation since the 2000s** when bariatric surgery became widely covered in insurance plans through the ACA. Innovation ဂိုဂိုဂို There can be >60% rebound weight gain if GLP-1s are ဂိုဂိုဂို abruptly discontinued. The 10% – 15% reduction in weight with continuous use of GLP-1s projects **3 million fewer people with obesity**, preventing up to 1.5 million heart attacks, strokes, and other adverse cardiovascular **Cost Impact** events over the next 10 years.



### **GLP-1** Future State — Anti-Obesity and Diabetes GLP-1 Coverage

GLP-1	Route	Frequency	Indication	Generic Launch
Bydureon	Injection	Weekly	Diabetes	2031
Byetta	Injection	Twice daily	Diabetes	2024 into 2025
Mounjaro (tirzepatide)	Injection	Weekly	Diabetes	2039
Ozempic (semaglutide)	Injection	Weekly	Diabetes	2032
Rybelsus (semaglutide)	Oral	Daily	Diabetes	2033
Saxenda (liraglutide)	Injection	Daily	Weight Loss	2026
Trulicity (duraglutide)	Injection	Weekly	Diabetes	Possibly 2024
Victoza (liraglutide)	Injection	Daily	Diabetes	2023 into 2024
Wegovy (semaglutide)	Injection	Weekly	Weight Loss	2032
Zepbound (tirzepatide)	Injection	Weekly	Weight Loss	TBD

Zepbound FDA approved for weight loss on 11/8/2023

Overall pipeline:

- 2 products Phase 3
- 19 products Phase 2
- 32 products Phase 1

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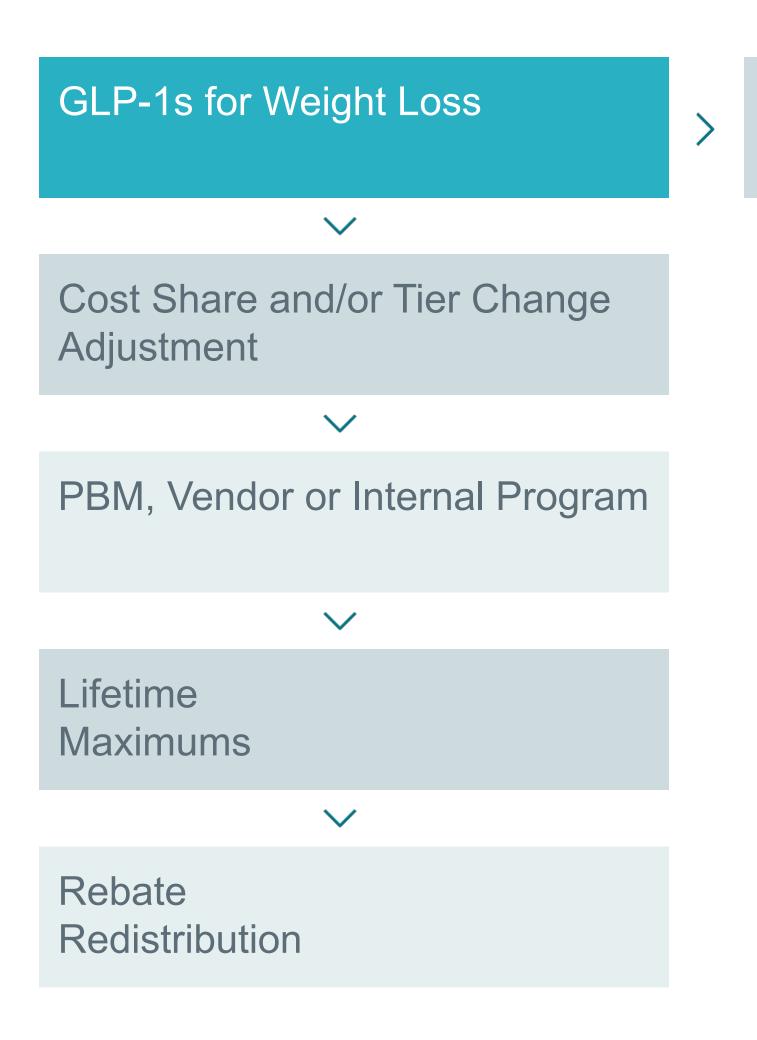


n oral version of Rybelsus the 25mg and 50mg vel is in phase 3 for abetes and weight loss	Competition may take years to reduce costs; generics for leading products not expected before 2032	Newer drugs working in different ways that increa effectiveness
----------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------





### Holistic Management Strategies: GLP-1s





#### Strict Utilization

Management

level

- Only select providers can prescribe GLP-1s for weight loss
- Increasing BMI requirements above FDA
- Documentation and chart notes required
- Participation in a weight loss program
- Full custom policy development with strict step therapy



Rebates may be affected by innovative management strategies for GLP-1s.

Aon Pharmacy is helping to shape the market. We engage executive PBM leadership to facilitate compatibility of marketplace solutions.

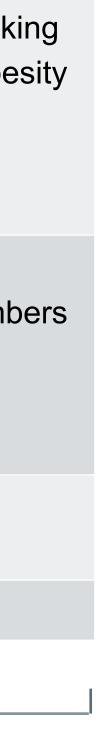


## How Employers are Addressing GLP-1 Coverage for Obesity

Unrestricted	<b>Minimal Restriction</b>	Restrictive	No Coverage
<ul> <li>Fully cover all GLP-1s without restriction</li> </ul>	<ul> <li>Prior auth requirements aligned with FDA approval guidelines</li> </ul>	<ul> <li>Require documentation of prior lifestyle modification treatment/ engagement for sustained time frame (ex: 3-6 months) for first prescription fill</li> </ul>	<ul> <li>No coverage for members seeking GLP-1s for the treatment of obes</li> </ul>
<ul> <li>Members accessing both Ozempic and Wegovy for weight loss use</li> </ul>	<ul> <li>A BMI ≥27 in persons with ≥1 weight-related coexisting condition</li> <li>OR BMI ≥ 30 alone and documentation of lifestyle modification counseling</li> </ul>	<ul> <li>Ongoing engagement in behavior change program for prescription refills</li> <li>Step therapy approach</li> </ul>	<ul> <li>Continue to cover GLP-1s approved for diabetes for member with a diagnosis of diabetes</li> </ul>
<ul> <li>No cost containment — very few employers left in this category</li> </ul>	<ul> <li>Minimal cost containment</li> </ul>	<ul> <li>Mitigates cost, positions member for best outcome</li> </ul>	
<ul> <li>No pharmacy rebate loss</li> </ul>	<ul> <li>No pharmacy rebate loss</li> </ul>	<ul> <li>Risk for pharmacy rebate loss</li> </ul>	

Variations exist across the spectrum



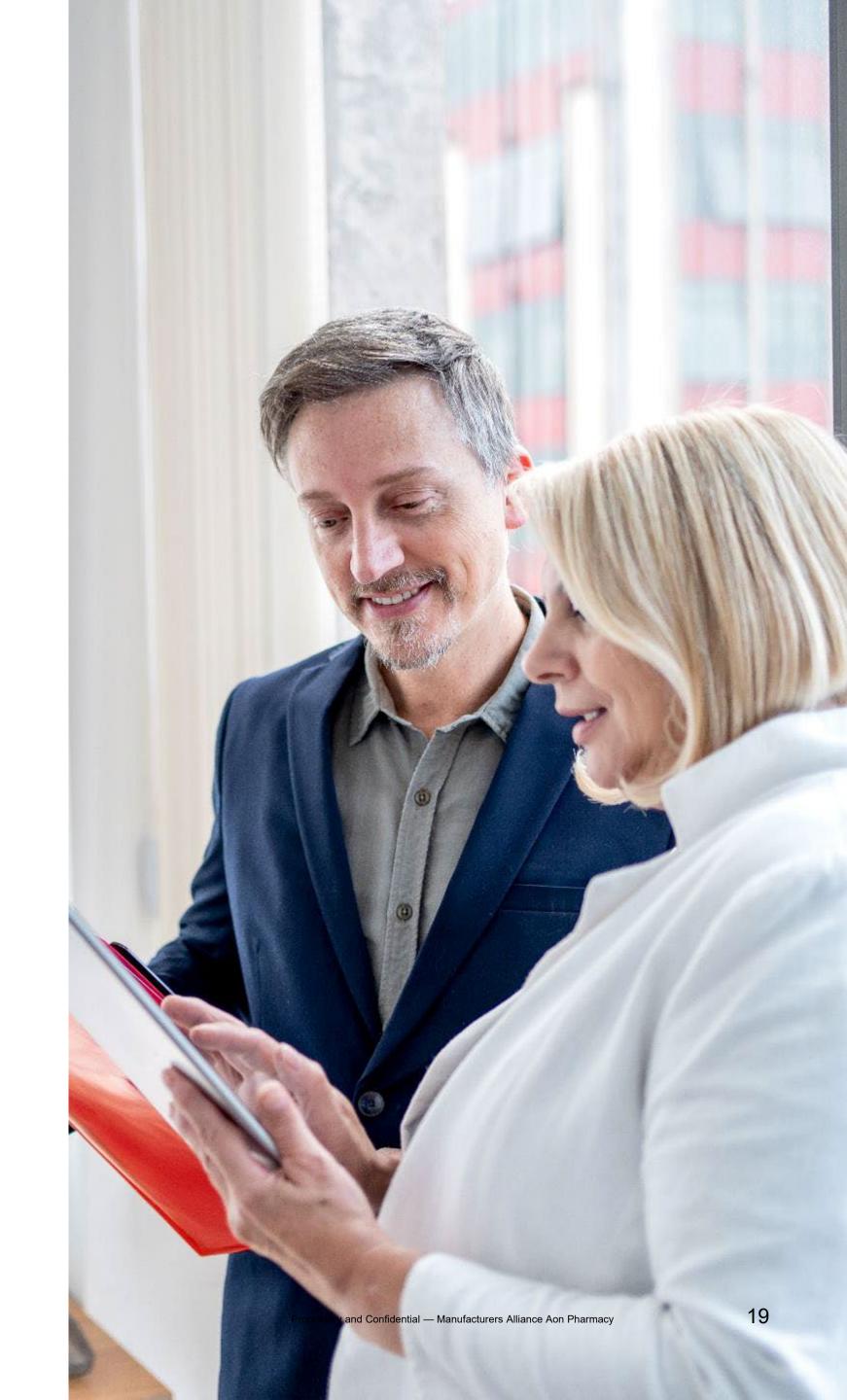




### **GLP-1** Discussions We're Having With Our Clients

- Dynamic coverage landscape means today's strategy may NOT be tomorrow's strategy in managing GLP-1s.
- GLP-1 coverage decisions can be heavily impacted by objective and subjective payor priorities, which vary significantly by industry, demographics, competitive landscape and corporate culture.
- If you haven't set a GLP-1 strategy, or if you lack confidence in your ability to articulate your current strategy within your organization, please talk to your AE about setting up time with our Pharmacy team.







### Biosimilars and Gene and Cell Therapy





## What's Going on in the Biosimilar Space?

Biosimilars are Complex

- Patent expirations don't mean availability of treatments.
- Dosing and product versions impact timing of releases to the market.
- The ability to interchange vs. substitute products impacts uptake.

Manufacturers and PBMs Will Make Changes to Adapt

- Manufacturers are positioning new treatments to grab the market, i.e., Skyrizi.
- Initially, rebates may reduce the treatment cost vs. the biosimilar cost.
- As the market evolves, rebate guarantee reductions may occur.
- PBM strategies have emerged with CVS effective 4/1 and ESI launched 4/25.

<sup>1</sup> Aon Pharmacy Coalition and direct contracts created with Aon include our agreed upon language for all three main PBMs and some others.



Given how Difficult it is to Predict These Changes, What are the Best Approaches

• PBM Contract language is being modified due to potential rebate losses.<sup>1</sup>

• Client's need advice on this rebate language changes.

• PBM approaches should secure lowest net cost with PA, step-therapy or copay drivers.



### Humira Biosimilars — Early 2024 Product Updates

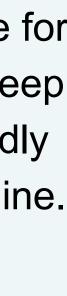
#### Table. Adalimumab Biosimilars That are Approved or Under Review With the FDA

Brand	Non-Proprietary Name	Company	FDA Approval	Launch Date	Interchangeability Designation?	High/Low- Concentration ?	Citrate-Free?
Amjevita	adalimumab-atto	Amgen	September 2016; approval for high- concentration version expected in 2024	Launched; high- concentration version expected in 2024	No	Low; high- concentration version in phase 3 trials	Yes
Cyltezo	adalimumab-adbm	Boehringer Ingelheim	August 2017	Launched in July 2023	Yes	Low	Yes
Hadlima	adalimumab-bwwd	Organon/Samsung Bioepis	July 2019	Launched in July 2023	No; Application for interchangeability is under review	Both	No for low- concentration; Yes for high- concentration
Hulio	adalimumab-fkjp	Mylan/Viatris/Biocon/Fu jifilm Kyowa Kirin	July 2020	Launched in July 2023	No	Low	Yes
Yusimry	adalimumab-aqvh	Coherus BioSciences	December 2021	Launched in July 2023	No	Low	Yes
Abrilada	adalimumab-afzb	Pfizer	November 2019	November 2023	Yes	Low	Yes
Hyrimoz	adalimumab-adaz	Sandoz/Novartis	October 2018	Launched in July 2023	No	Both	No for low- concentration; Yes for high- concentration
Idacio	adalimumab-aacf	Fresenius Kabi	December 2022	Launched in July 2023	No	Low	Yes
Yuflyma	adalimumab-aaty	Celltrion	May 2023	Launched in July 2023	Filed application to conduct trial investigating interchangeability	High	Yes
AVT02	N/A	Alvotech/Teva Pharmaceuticals	Approval pending	2024 pending approval	Application for interchangeability is under review (expected in Q4 2024)	High	Yes



It's impossible for sponsors to keep up with a rapidly evolving pipeline. Building an adaptive strategy with your consultant is critical.

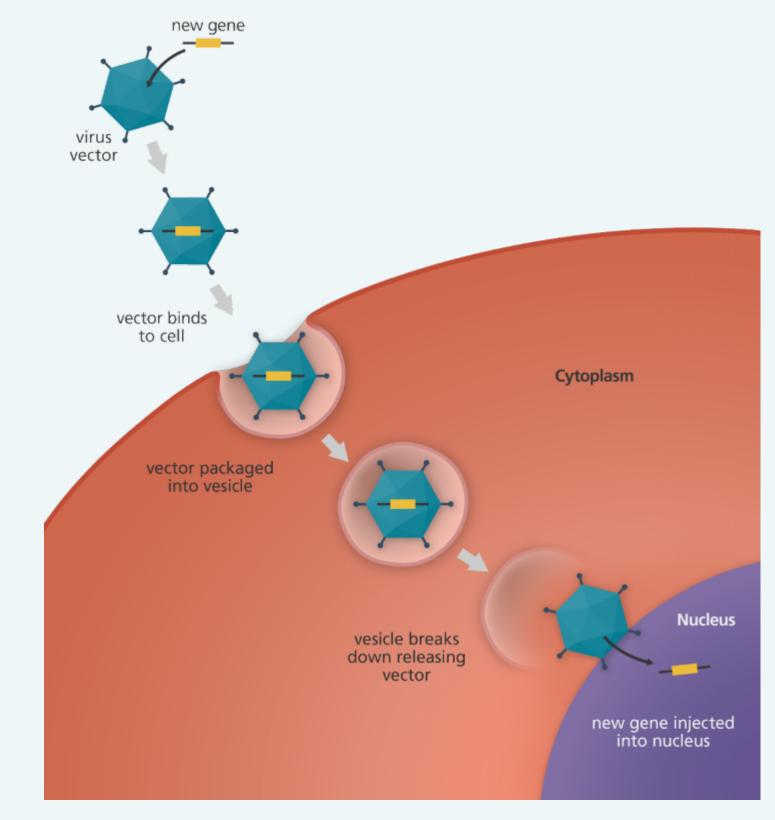
Last updated: January 30, 2024 Data from AJMC — The Center for Biosimilars





### Gene and Cell Therapies: The Science is Pretty Amazing!

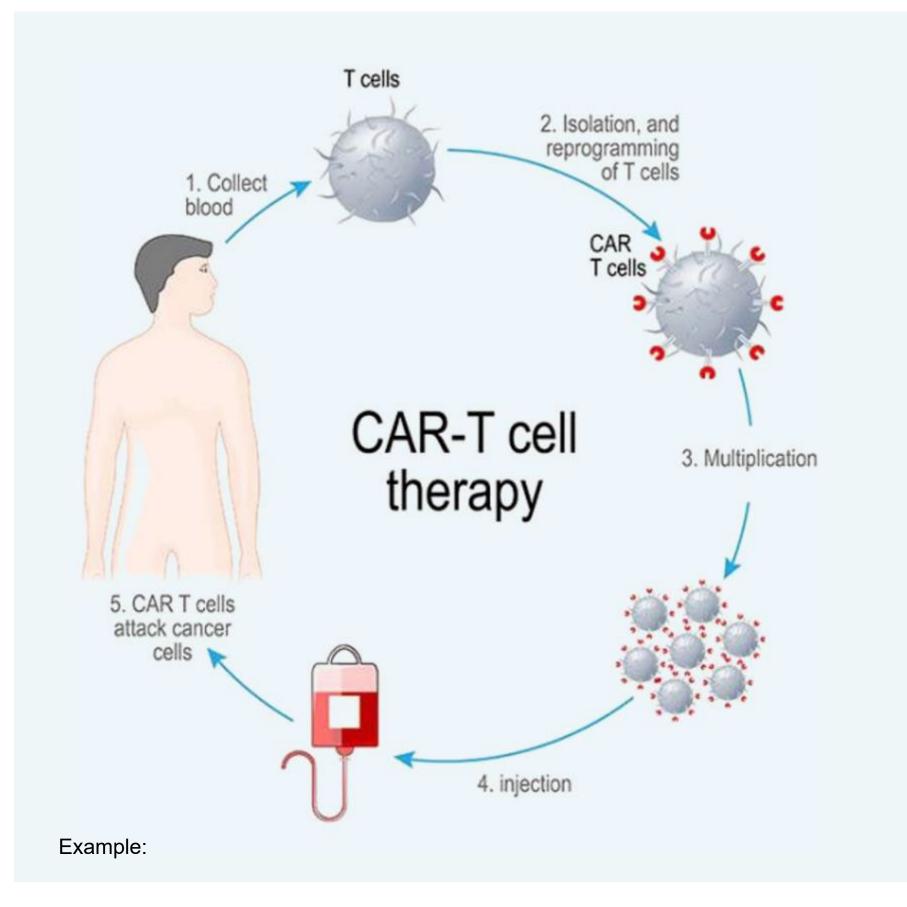
#### **Gene Therapy**



Examples: Lenmeldy (\$4.2M, one-time); Lyfgenia (\$3.1M, Sickle Cell Disease)

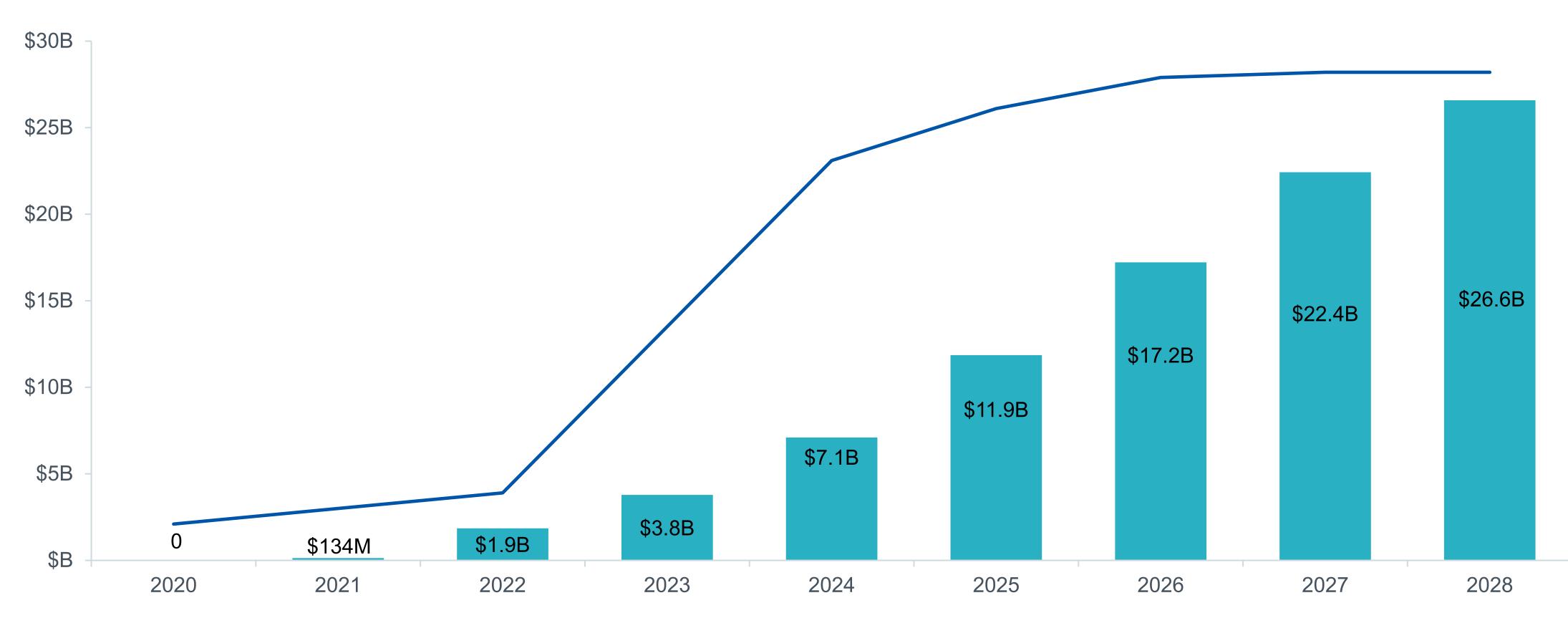


#### **Cell Therapy**



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### **Unprecedented Increase in Ultra-High-Cost CGTs, Total Plan Spend**







### Real-Time Monitoring of Brand, Specialty and Gene Therapy Pipelines

#### **Upcoming Biosimilar Launches**

Estimated Launch Date/Launch Probability	Biosimilar Name/Status	Competitors	Reference Drug Name	Brand Companies	U.S. Brand Sales (2023)
1H 2024 (70%)	Hercessi; Hanquyou; HLX02; Trastucip; Tuzucip; Zercepac (Approved)	Henlius; Accord; Intas	Herceptin	Roche; Genentech	\$559M
2024 (60%) or 2025 – 2027 (30%) or 2031 – 2036 (10%)	Tyruko (Approved)	Polpharma; Sandoz	Tysabri IV	Biogen; Royalty Pharma	\$1,663M

#### **Upcoming Gene Therapy and Specialty Launches**

Pipeline Drug Name	Brand Company	Route
Elevidys Delandistrogene M…	Sarepta	Intravenous
Kresladi Marnetegragene Au…	Rocket Pharma	Intravenous
Edurant Rilpivirine Hydrochl	Tibotec Johnson & Johnson	Oral

Pipeline information provided by IPD Analytics.



Mechanism of Action	Indication	Stage
Gene therapy	Duchenne muscular dystrop…	Pending (6/21/2024)
Gene therapy	Leukocyte adhesion deficie	Pending (6/30/2024)
Non- nucleoside rever	HIV-1 infection	Pending (2Q 2024)

### Pharmacy insights connected into Aon's Total Benefits Strategy:

- Actuary partners with Pharmacy to finetune budget impact models
- Aon Teams work collectively to explore Stop Loss and Reinsurance solutions alongside carrier programs
- Clinical Pharmacy considerations are factored into Wellness Solutions and Time Away and Leave solutions



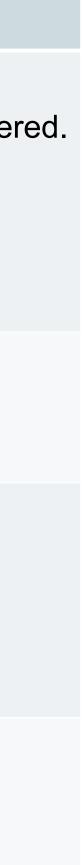
### **Gene Therapy Solutions**

Available Solutions	Comments
Stop Loss and Stop Loss Carve Out/PBM	<ul> <li>Most programs are limited</li> <li>Known members with get (e.g., Newborn during plated)</li> <li>Limited number of therapy</li> <li>Therapy-only coverage results</li> <li>No guarantee future therapy</li> </ul>
Reinsurance	<ul> <li>Generally covered in line</li> <li>Cover all gene therapies</li> <li>Look for possible lasers of</li> </ul>
Financing	<ul> <li>Establishing line of credit</li> <li>Flexibility in types of cove</li> <li>Does not function as insu</li> <li>Not just for gene therapy infants</li> </ul>
Provider Networks and Value-Based Contracting	<ul> <li>Contracting for gene there</li> <li>Trying to "solve" for accession</li> <li>Look for blockchain solution</li> </ul>



- ed to their customers
- ene therapy conditions are excluded such that only members new to the plan are covered. lan year or adding spouse after marriage in plan year)
- apies are included
- no related care coverage
- rapies will be added to the "formulary" and at "what price"
- e with other high costs
- s and related care
- or contingent lasers for enrollees with known conditions
- lit to be accessed only when needed
- verage (specific therapies, in aggregate, coordination with stop loss contracts) surance
- y. Can customize to what you would like covered, e.g., gene therapy and premature

erapy product at or close to wholesale acquisition cost (WAC) ess to value-based contract arrangements, including warranties utions





### **Discussion Summary and Aon Guidance**

Challenges to the status quo within the vertically integrated PBM landscape

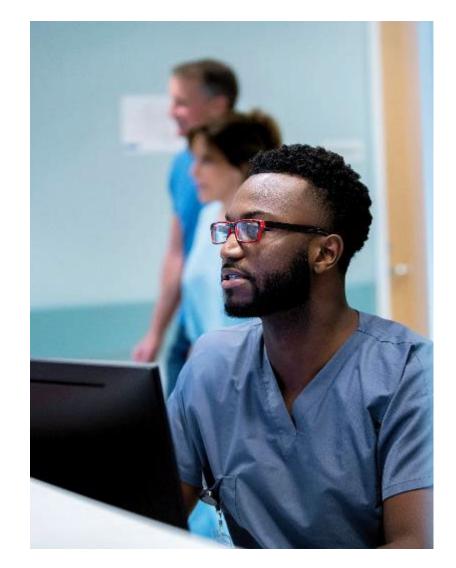
**GLP-1s** have changed everything and will continue to grow in cost and utilization

- Pharmacy contract and coverage reviews are essential



**Biosimilars are** a complex and evolving class that require strategies to address expansion

Gene and cell therapy pipeline will explode in 2025 and surpass \$25B by 2028



• GLP-1 and Biosimilars require active management of potential impacts to rebate contract language

• CY 2025 strategy discussions should include financing 2026 gene and cell therapies





## Thank You



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