EBPA Presentation

EMERGING TRENDS AND STRATEGIES IN PHARMACY BENEFITS

CBIZ

Your Team.

Local. Trusted. Nationwide.

AGENDA

- Trends and drivers
- PBM Coalitions / Consortiums
- Specialty Carve out
- Alternate Funding

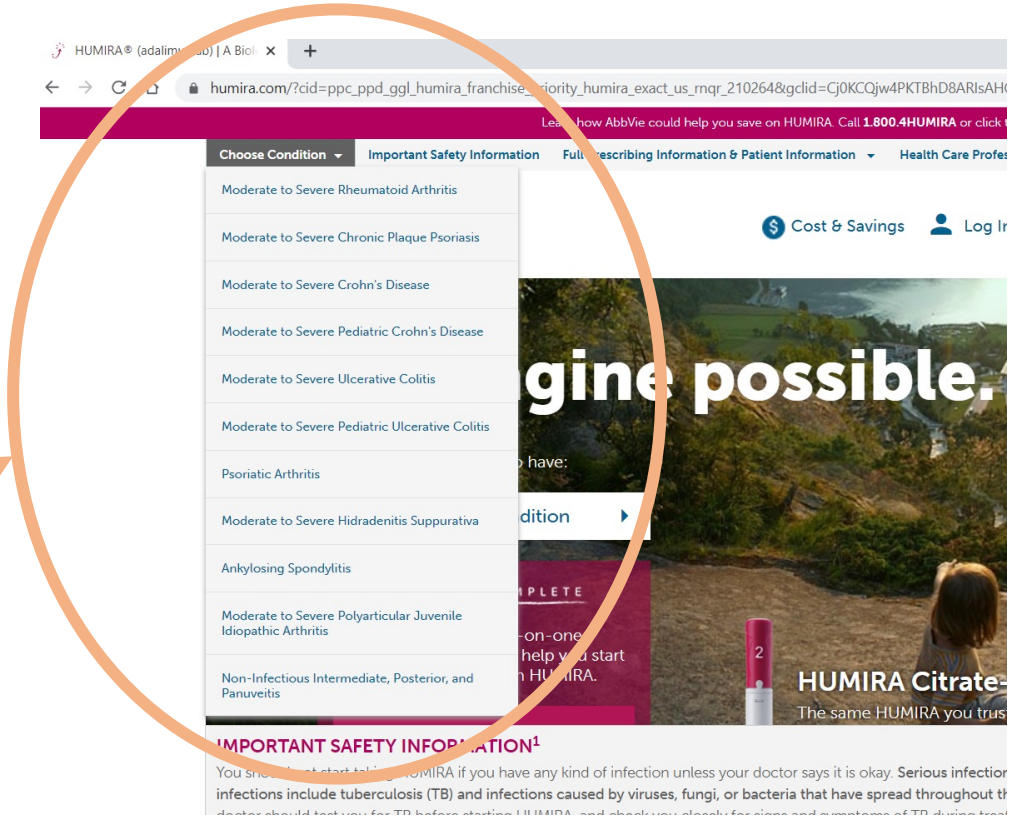
Pharmacy Trends

INDUSTRY TRENDS

- Pharmacy trends have been staggering, and unsustainable in recent years
- Trend drivers include;
- High brand price inflation: ~10%/year
- High new to market pricing: >$500,000/year (multi-million dollar therapies on the horizon)
- Increased utilization due to aging population
- Increased utilization due to expanded indications of current therapies (many in specialty class)

PHARMACY IS A CONCERN FOR CLIENTS

- Expanded Indications
  - Humira originally approved in 2002 for RA
  - Expanded indications

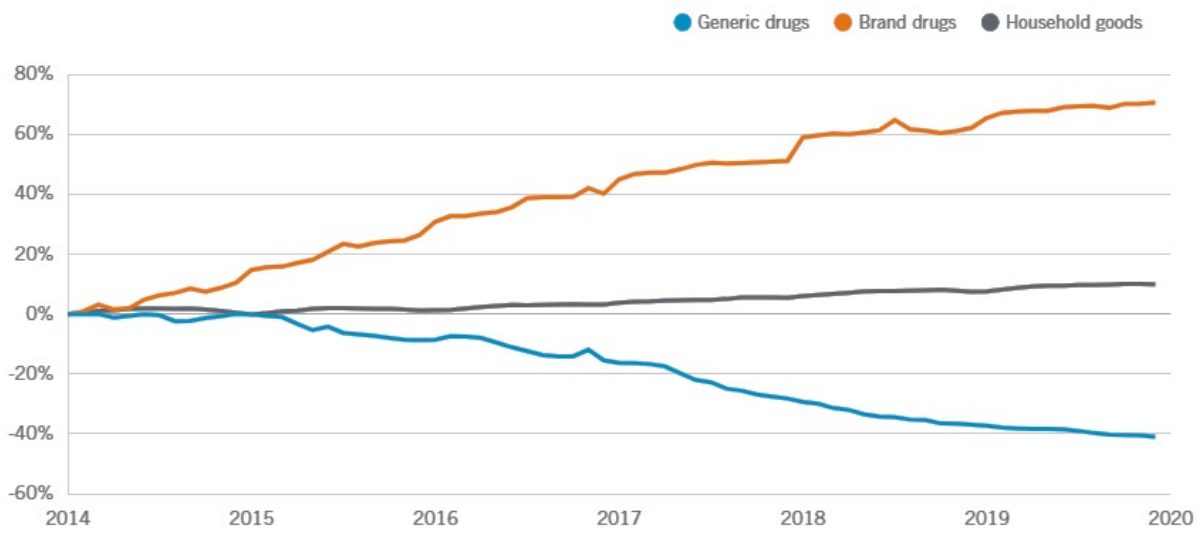


- Increased Utilization
  - Increased utilization due to aging population
  - Direct to Consumer Advertising
  - Drugs Coming to Market More Quickly
  - Manufacturers throwing anything at the wall to see if it sticks

PHARMACY IS A CONCERN FOR CLIENTS (CONT'D)

- Brand Price Inflation
  - 3-4x Rate of Inflation

Express Scripts prescription price index, 2014-2019



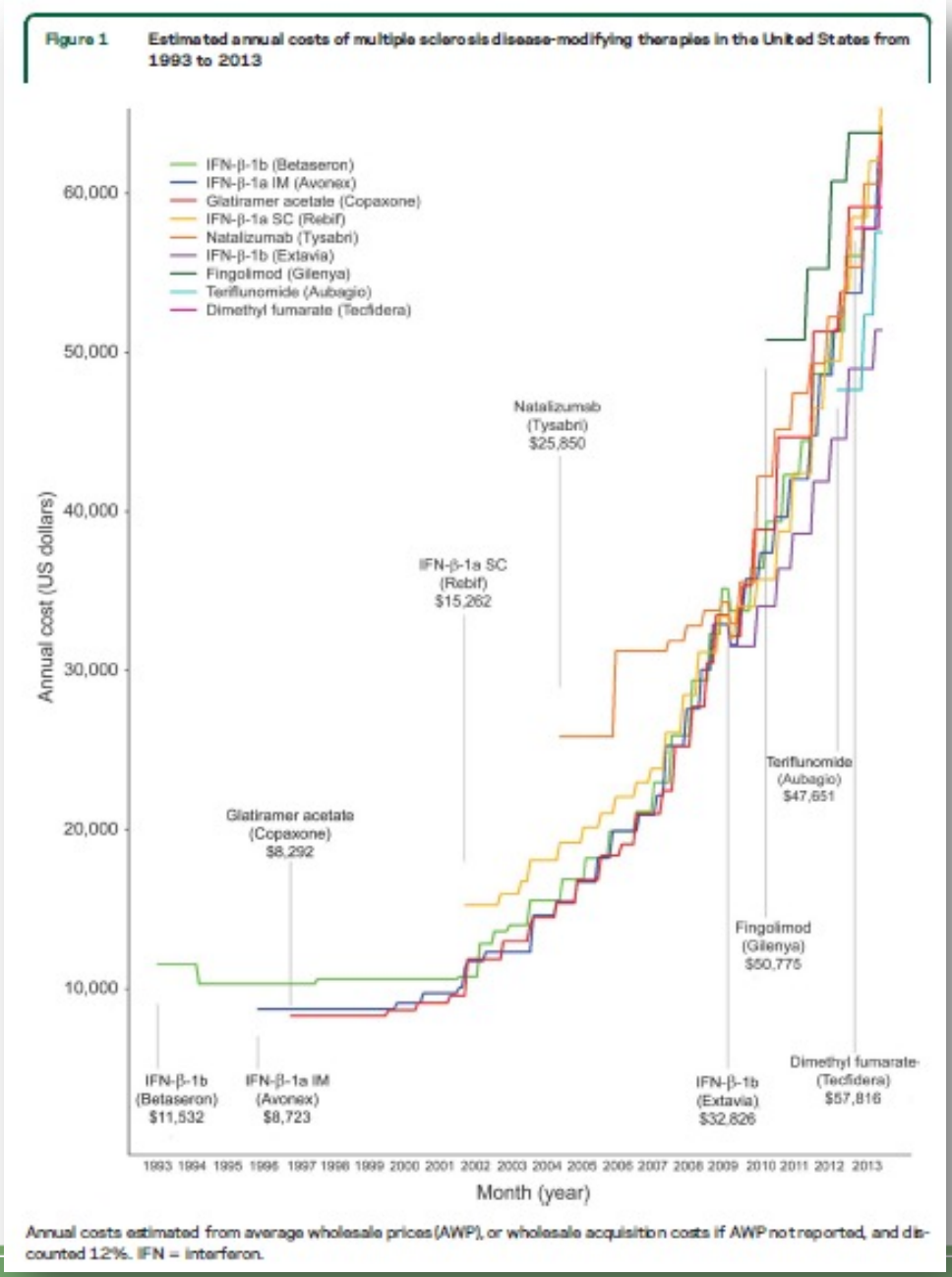
- Specialty & Extreme Cost Drugs
  - $500K+ Medications
  - Gene Therapies

ESI 2019 drug trend report accessed online -https://www.express-scripts.com/corporate/drug-trend-report#a-vision-for-2020-and-beyond

Pharmacy Trends

Inflation

- Contrary to traditional market pressures, prices *increase* with competition



DM Hartung, DN Bourdette, SM Ahmed, et al. The Cost of multiple sclerosis drugs in the US and pharmaceutical industry – Too big to fail? Neurology 84 May 26, 2015, 2185-2192

Pharmacy Trends

High new to market pricing

- Specialty Drug
- Limited Distribution
- $7,500 / month

Tecfidera (dimethyl fumarate) delayed-release capsules 240 mg

TECFIDERA effectiveness

Understanding the potential benefits of TECFIDERA

In separate 2-year clinical studies, TECFIDERA was tested against a placebo, or "fake" pill—a standard way to measure if a drug works as expected. See below to learn more about the trial results and benefits of TECFIDERA.

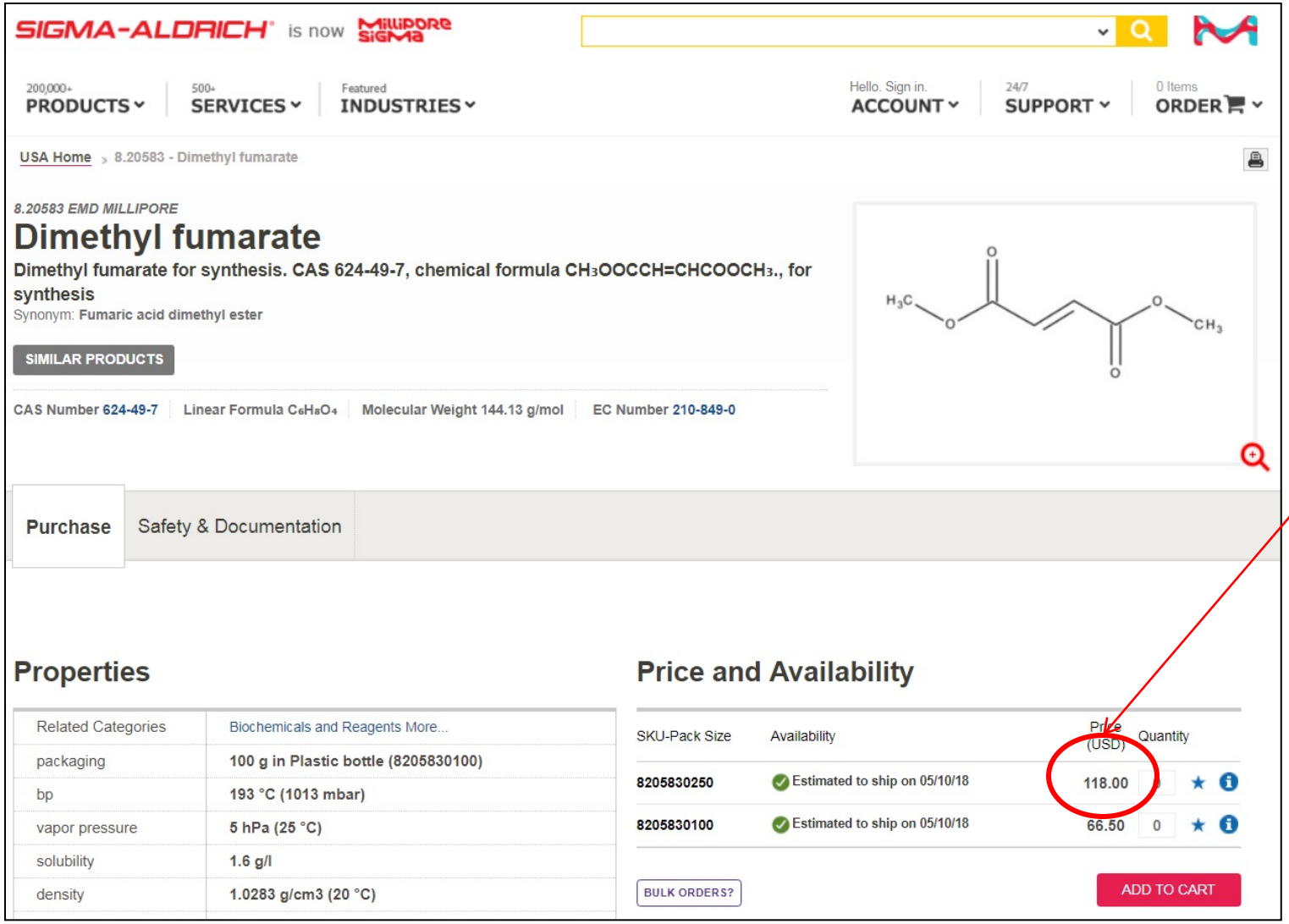
TECFIDERA was shown to:

Cut
RELAPSES IN HALF
→ Know more

Delay
PROGRESSION OF PHYSICAL DISABILITY
→ Discover how

Slow
DEVELOPMENT OF BRAIN LESIONS
→ Get the details

Pharmacy Trends



That is **$6.80** for 1 month of drug therapy!!

Extreme Cost Medications – "Gene Therapy"

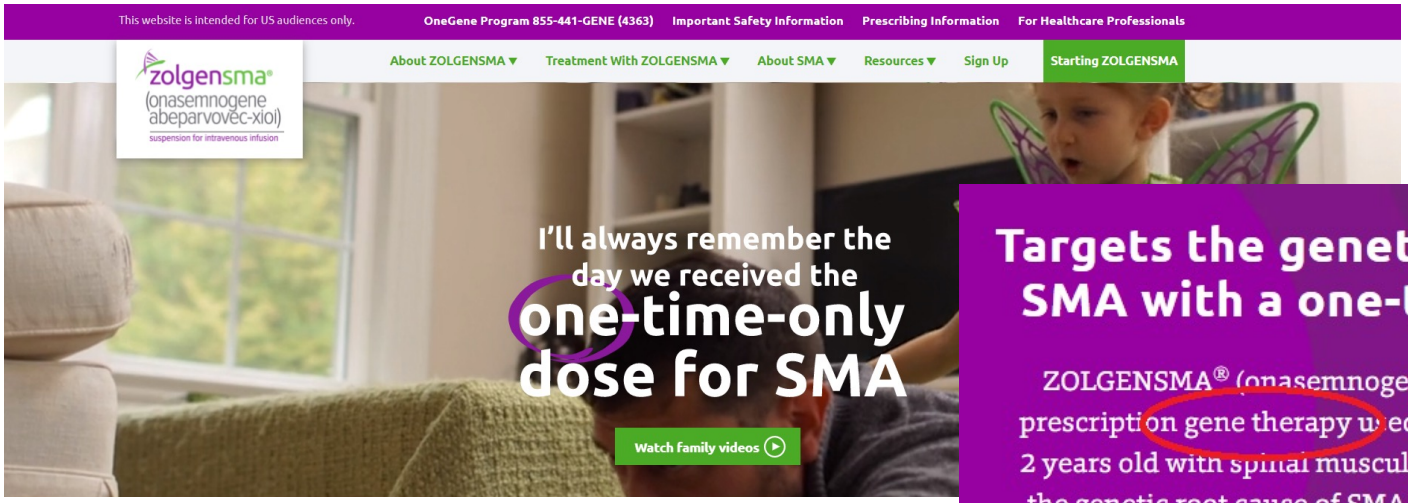
Zolgensma

- Spinal Muscular Atrophy (SMA)
  - Missing or non-working Survival Motor Neuron (SMA) gene.
  - Fatal, life-limiting, or severely debilitating disease
  - Types 0-4 (in order of most severe to least
- 1:10,000 live births
- Treats children less than 2 years old
- 1,400+ treated as of June 1, 2021
- Approved May 2019
- $2.1 Million Per Treatment

Luxturna

- Genetic Retinal Dystrophy
  - Inherited Retinal Disease (IRD)
  - Retinoid Isomerohydrolase (RPE65) Mutation
  - Fatal, life-limiting, or severely debilitating disease
  - Types 0-4 (in order of most severe to least
- 30:100,000 people have an IRD
- 1/10 of those have the specific type of congenital syndrome
- 2% of those have the gene mutation
- 1-2K patients in the US
- Approved December 2017
- $1 Million Per Treatment

Extreme Cost Medications



Targets the genetic root cause of SMA with a one-time-only dose

ZOLGENSMA® (onasemnogene abeparvovec-xioi) is a prescription gene therapy used to treat children less than 2 years old with spinal muscular atrophy (SMA). It targets the genetic root cause of SMA with a one-time-only dose and replaces the function of the missing or nonworking survival motor neuron 1 (*SMN1*) gene with a new, working copy of a human *SMN* gene.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ZOLGENSMA is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein. SMA is caused by a bi-allelic mutation in the *SMN1* gene, which results in insufficient SMN protein expression. Intravenous administration of ZOLGENSMA that results in cell transduction and expression of the SMN protein has been observed in two human case studies *[see Clinical Pharmacology (12.3)]*.

COVID-19 Products

PHARMACOLOGICAL PROPERTIES

Mechanism of Action

The Janssen COVID-19 Vaccine is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 (Ad26) vector that encodes a SARS-CoV-2 spike (S) protein in a stabilized conformation. The S protein on the surface of the coronavirus binds to the Angiotensin Converting Enzyme 2 (ACE2) receptor of a host cell allowing the virus to infect the cell. Vaccination with the Janssen COVID-19 Vaccine leads to humoral and cellular immune responses directed against the S protein and in particular the production of neutralizing and other functional S antibodies which may block ACE2 receptor binding to the S protein, contributing to protection against COVID-19.[6]

Search

Bloomberg

Prognosis

U.S. Reaches 75% of Adults With at Least One Vaccine Dose

By Josh Wingrove

September 7, 2021, 9:43 AM MDT *Updated on September 7, 2021, 11:53 AM MDT*

GENE THERAPY TRENDS

We anticipate that by 2020 we will be receiving more than 200 INDs per year, building upon our total of more than 800 active cell-based or directly administered gene therapy INDs currently on file with the FDA. **And by 2025, we predict that the FDA will be approving 10 to 20 cell and gene therapy products a year** based on an assessment of the current pipeline and the clinical success rates of these products.

~Statement From FDA commissioner Scott Gottlieb, M.D.

https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

EMERGING STATE REGULATIONS

PHARMACY STEERAGE AND PRICING

Rutledge v. Pharmaceutical Care Management Assoc.

- Unanimous (8-0) ruling issued on December 10, 2020.
- Supreme Court determined that States can regulate pharmacy benefit managers.
- A State's ability to regulate a pharmacy benefit manager's generic drug reimbursement rates is sufficiently distant such that ERISA federal preemption of state regulatory authority does not apply.
- Concerns: If each state can regulate a pharmacy benefit manager, it will be challenging for a multiple jurisdictional self-funded plan to control prescription drug costs efficiently.

EMERGING STATE REGULATIONS

PHARMACY STEERAGE AND PRICING

- State insurance law regulates insured plans
- Self-funded plans (excluding government and church plans) = ERISA preemption (limited State regulation authority)
- Pharmacy benefit manager State regulation = No ERISA preemption
- Concerns with pending legislation:
  - Mail order issues
  - Specialty pharmacy delivery issues
  - Preferred network availability issues
  - Payment restrictions

PBM Coalitions/Consortiums

CONCEPT

- Its harder for a PBM to service an individual client, therefore they target a higher revenue per claim
- Multiple employer groups band together under 1 contract
- Volume purchasing benefits – Discounts / Rebates
- More favorable terms and conditions (e.g. cleaner contract)
- Generally more favorable the smaller the group
    - <5,000 Employees – Makes a lot of sense
    - 5,000 – 10,000 Employees – Sometimes makes sense
    - 10,000 – May not make sense
- Not all coalitions are created equal!

COALITIONS

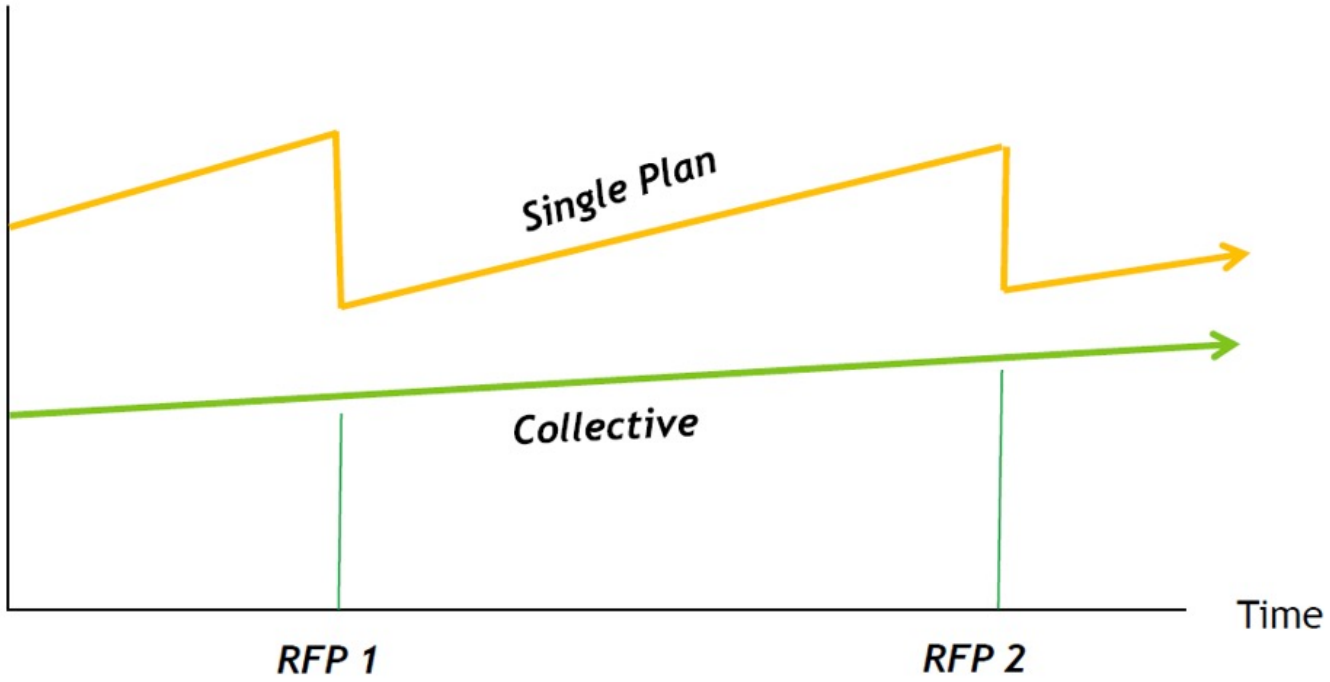
STRENGTHS

- Strong financials – volume purchasing
- More robust contract language
- More aggressive performance guarantees
- Dedicated account teams
- Additional support from the coalition
- Built-in escalators, market checks and audits

CONSIDERATIONS

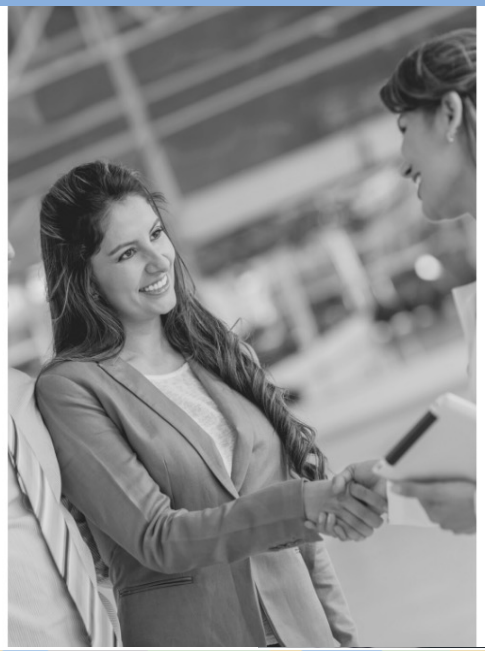
- Tight termination language
- Fees
- Access to data
- Tiers and pricing tactics
- Standard contract
- Client may give up their voice as part of the greater leverage
- Some performance guarantees measured at the coalition-level
- Limited PBM partners
- Protective measures during marketing years
- Sole source providers. Limited flexibility outside the PBM

FINANCIAL COLLECTIVE VALUE



Specialty Carve-out

VIVIO



CONCEPT

- Specialty makes up roughly 50% of drug spend (on the pharmacy benefit side)
- Most PBMs own/operate their own specialty pharmacy
- Most PBMs manage their own formulary (or leverage a PBM partner that does)
- Most PBMs manage their own clinical programs around specialty drugs (PA, ST, QL)
- Primary focus on cost – Discounts / Rebates

<u>What's the problem??</u>

- The PBM only gets paid when they get a paid claim
- They get paid more, the more the client pays
- Inherent fiduciary conflict of interest

STRATEGY

- Solution: Take it away from the PBM
- Install a vendor to manage the specialty drug benefit
- Focus attention on utilization first, then cost: Is it the right drug

Is this the right drug for me?

Is it a fair price?

Is it working for me?

Do you know the *answers* to these questions?

VIVIO

KEY DIFFERENTIATORS: MEMBER SUPPORT

Care Management for Complex Conditions

PERSONALIZED CARE

VIVIO's clinical team personalizes drug therapies for each and every member based on their unique medical history.

EMPOWERMENT

VIVIO clinicians are available to answer any questions that a member, or caregiver, may have about the data behind their condition and drug therapy.

CONCIERGE

VIVIO's member concierge team is there to help with any questions on plan design, shipping or anything else – whatever the problem, it is ours to solve.

FLEXIBILITY

Multiple pharmacy, delivery and site of care options to enhance member convenience.

KEY DIFFERENTIATORS: BUSINESS

Customers know what they are paying for and what they get in return

TRANSPARENT PASS THRU

Our admin fee is our sole source of revenue and we put that fee 100% at risk through ROI guarantees.

DRUG PRICE INFLATION

We are paid the same whether drug prices go up or down. Occasionally, we recommend more expensive therapies, but typically there are less expensive options.

DATA OWNERSHIP

Customers own their data and VIVIO owns the data that we derive from it. We don't sell customer data to anyone.

PROVIDER OWNERSHIP

VIVIO doesn't own any service providers and is purely a data intermediary.

COPAY CARDS

We consider manufacturer sponsored programs such as copay assistance, patient assistance and similar programs to be a net discount in the marketplace.

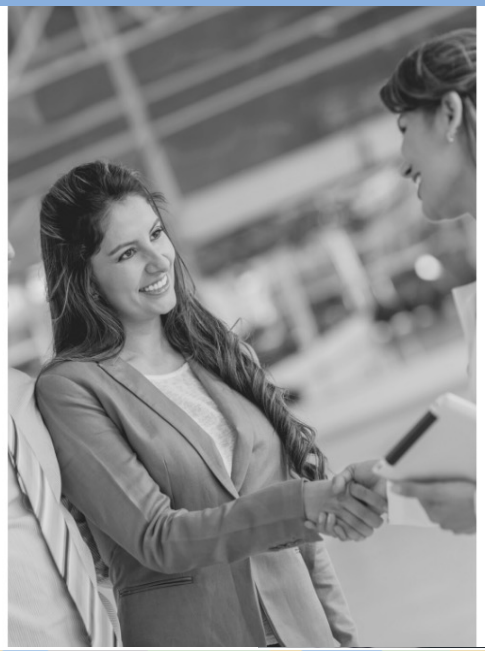
PUBLIC BENEFIT CORPORATION

Our corporate structure is tied to the public benefit of taking dollars out of the healthcare system and putting them back into the hands of Americans.

CONSIDERATIONS

- Finding vendor partners who will collaborate well
- Understanding the push/pull of contractual discounts, rebates, and utilization trends
- Member perception of benefit offering

Alternate Funding



CONCEPT

- Alternate Funding Model
- Taps into Pharmaceutical Manufacturer Corporate Social Responsibility (CSR) programs
- CSRs may include; private/public charities, State/County/Municipal programs
- CSRs provide access to drugs/copay assistance only available to under insured or functionally uninsured patients
- Plan excludes certain drugs, forces 100% member cost share which is later picked up by the CSR program
- Drug spend is removed from the plan and member receives the drug at no cost

STRATEGY

- Funding is not specifically designed for the indigent
- Funding is earmarked for the patient, not the plan sponsor
- A patient who is under insured, or functionally uninsured may access these funds
- Pushing higher out of pocket costs to the members drives them into a functionally uninsured state

MEMBER IMPACT

- The plan change has the effect of excluding certain drugs from plan coverage
- Impacted members are connected with an advocate who works with them to enroll in CSR programs
- Member may have to complete additional enrollment forms and send personal health/financial information to the advocacy program
- Member still receives their drug, many times at no cost to them

THE PLAN IMPACT

- The plan change effectively pushes plan expense onto the member, which is later picked up by the CSR program
- Plan has a contingency in place in a case where no CSR program is available for a specific medication
- Financial impact will vary based on the number of drugs targeted
  - Only extreme cost drugs (>$500,000/yr) – low impact, low savings (less than 0.1% fills)
  - All specialty drugs – low/moderate impact, high savings (less than 2% fills)
  - All brand drugs over $350 – moderate/high impact, high savings (less than 10% fills)

CONCERNS

Member disruption

- This will not be the typical transaction a member is used to – learning something new
- Potentially clunky handoff between stakeholders; member, physician, dispensing pharmacy, PBM, advocacy program, CSR program
- Apprehension around sharing personal health/financial info
- Perception of benefit offering

Long term viability

- Primarily seeing this solution in the small-mid market.
- Uncertainty around whether this is a 1-3 year solution, or something to stand the test of time
- Stop loss- When drugs are excluded but ultimately covered if advocacy fails

Legal Validation

- Profiling - These must be strategic, global program changes, not targeting specific individuals
- HIPAA
- Fraud – the plan, and member must not be put in a position where they are falsely claiming dollars from a charity or CSR

PLAN SPONSOR QUESTIONS

Contract Management

- Do we have a well managed pharmacy contract?
- When was the last time we bid-out our pharmacy plan? (if carved-in, have we looked at a stand-alone PBM option?)
- Are we currently receiving pharmacy rebates? (if so, what are the value of those rebates?)
- Am I spending over $2M/year on pharmacy?
- What kind of advisement are we getting on our pharmacy plan? Who is that advisement coming from?

Utilization Patterns

- What have our annual trends been on pharmacy the last few years?
- How effective is our plan design in promoting our members to be better consumers?
- What clinical programs are we currently enrolled in and how effective are they?
- What other clinical programs are available to us?
- What is our risk tolerance for novel pharmacy solutions? How will that impact members?


YOUR TEAM
IS HERE TO HELP
Connect with us at cbiz.com
CBIZ