Learning about “Specialty Carve Out’s” and What it Means for Industry Moving Forward

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- Understand the compliance and ethics associated with alternative funding programs
- Explore recent responses to these cases
- Navigate programs moving forward and the effect on patient assistance

Agenda

- Self Insured Employers Challenges for Benefits Management
- Specialty Capture/Alternative Funding Sources
- Players and Their Pitch
- Adverse Consequences: Real and Potential
- Plan of Action for Change

Self Insured Employers Challenges for Benefits Management

Self-Insured Employers

NAHPC

-Top 10 most expensive US drugs – over $630,000 to over $2 million annually

-Growing specialty drugs and biosimilars in pipeline

- Specialty Medicines are nearly 50% of a plan's total drug spend

  - About 35% of those are in Medical Benefits

National Alliance of healthcare Purchaser Coalitions 2021 Annual Report - file:///C:/Users/User/Downloads/NA%20Annual%20Report_2021_FNL2.pdf

Target: High-Cost Claims

Rethinking How We Mitigate *HIGH-COST CLAIMS*

The Problem: Few (if any) employers have the size, resources or focus to address rapidly escalating high-cost claims. ***Since 2016, the number of health plan members with claims $3M+ has doubled***, heightening sustainability concerns. Elimination of annual and lifetime maximums through the Affordable Care Act and the dysfunction of the reinsurance market has made this a top priority for every employer, purchaser and market.

High-Cost Claims Defined:

- Unpredictable/infrequent for individual employers
- Claims costing $50,000 or more per year
- Cost outliers that are frequently lasered (i.e., stop-loss insurance covers only the first year of claims, then will cover everything except that claim)
- Often for severe, debilitating disease conditions

Facts about high-cost claimants

JUST **1.2%**

OF ALL HEALTH PLAN MEMBERS ARE HIGH-COST CLAIMANTS

...but they make up 1/3 of total health care spending

29x

Average member cost

$122,382

Average annual cost

53% CHRONIC CONDITIONS

47% ACUTE CONDITIONS

Wellmark Blue@Work

"High-cost claims are the biggest threat to employer-sponsored healthcare coverage today. Only through collective employer action can these risks be mitigated."

Michael Thompson
National Alliance President & CEO

Strategies will vary based on duration of expenditures and quality or quantity of options

	Multiple Effective Options	*Limited Options*
Long-duration Treatment	Hemophilia Multiple sclerosis Multiple myeloma Autoimmune Cystic fibrosis End-stage renal disease (ESRD) Hereditary angioedema	Spinal muscular atrophy Metastatic cancers Duchenne muscular dystrophy Immune globulin (palliative) Congenital anomalies (lifelong)
Short-duration Treatment	Lymphoma Premature birth Spine surgeries Immune globulin (therapeutic) Inherited retinal dystrophy (RPE65)	Spinal muscular atrophy Neutrotrophic keratitis Transplant Congenital anomalies Idiopathic pulmonary fibrosis Sepsis Trauma and burns

National Alliance Offers Tools to Build the Bridge to Sustainability

- Mitigating High-cost Claims: A Closer Look at Hemophilia
- Employer Rx Value Report and Value Framework Infographic
- Hospital Payment Strategies: Setting Price & Quality Expectations

National Alliance of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

NAHPC Strategies to Reduce Drug Costs

Be Proactive, not Reactive

Specific Saving Strategies for High-Cost Medical Drugs

Learn more: *Achieving Accountabilty & Predictibility on the Medical Side of Drug Benefits*

CLINICAL RIGOR

- Separation of dispensing/rebates from clinical functions
- Independent, expert clinical management
- Cost-effective step therapy, when appropriate
- Elimination of waste
- Same level of clinical rigor applied to to specialty drugs on medical side
- Longer term – increased specialization

COST-EFFECTIVE SOURCING

- Better align co-pay and patient assistance programs
- Unrestricted, competitive dispensing options and sources
- Site-of-care optimization for provider-administered drugs
- Longer term – collective management & stewardship

Contracting Strategies

- Deconflict PBM and medical carrier relationships (fiduciary compliant)
- Reduced/fixed markups for provider buy/bill drugs
- Outcomes-based drug pricing
  - Specialty generics filled in retail, not at specialty pharmacy
  - Payment amortization (pay-over-time)
  - Hospital at home/telehealth
  - Narrow networks
  - More timely and transparent reporting
  - Bill review/negotiation
- Longer term – population-based hybrid contracts

Plan Design Strategies

- All drug management under the pharmacy benefit
- Dose rounding protocols (for injectables)
- More rigorous utilization management for high-cost drugs
  - PA/pre-certification functions
  - Preferred drug lists/formularies
  - Quantity limits
  - Step therapy
  - Specialty carve out
  - Exclusions/coverage limitations
- Aligned financial incentives with plan participants
- Leverage secondary coverage when available (e.g., spouse employer, Medicaid or Medicare)
- Longer term - Steerage to improve quality, appropriateness and reduce impact of middlemen

Integrate Core Pillars of Overall Risk and Cost Reduction

There is no one-size-fits-all approach to tackle the broad spectrum of high-cost claims; a combination of options is needed for each case

1 Prevention

- Genetic testing (pre- and postpartum)
- Education
- Risk factor identification
- Enhanced care/utilization management
- Plan design

2 Optimal Care

- Right diagnosis & treatment
- Appropriate care goals
- Billing/coding accuracy; fraud/waste/abuse flags

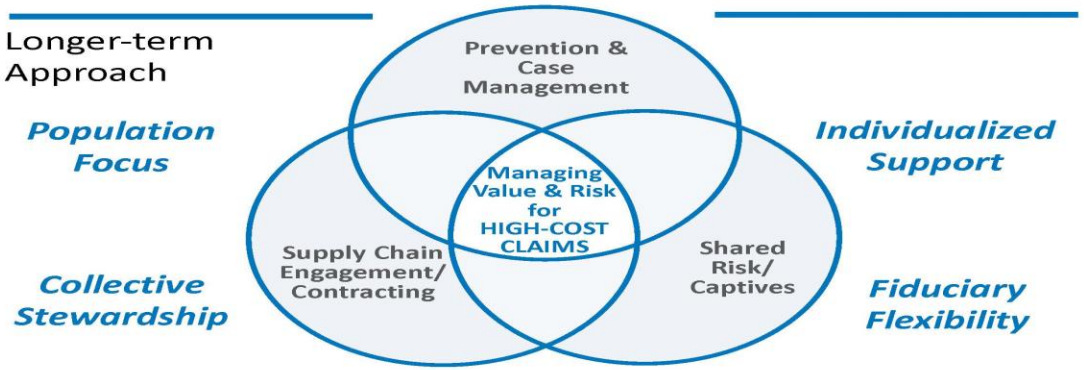
Stop Loss | Short-term | Long-term | *Reduce Acquisition Cost* | *Cost Sharing* | *Risk Shifting*

3 Collective Stewardship

- Diverse & evolving priority areas
- CAPTIVE development
- Population level cost/ROI evaluation
- Plan design alignment
- Innovative contracting
- Real-time data mining
- Forward focus

CONTINUOUSLY REEXAMINE PATIENT EDUCATION, INVOLVEMENT AND ACCOUNTABILITY TO ENSURE SUSTAINABLE PATIENT ENGAGEMENT

Longer-term Approach



National Alliance of Healthcare Purchaser Coalitions | 1015 18th Street, NW, Suite 705 Washington, DC 20036 | (202) 775-9300 | nationalalliancehealth.org |twitter.com/ntlalliancehlth | linkedin.com/company/national-alliance/ 06/21

Growing Interest in Alternative Funding Models

- 2022 Pharmaceutical Strategies Report
  - 8% of benefits leader respondents (employers, unions, health plans) use and alternative funding model
  - 31% exploring use
- 2022 Gallgher Research & Insights Emplyer Market Trends
  - 10% of self-insured employers with at least 5,000 employees use now
  - 8% planning to use withing 2 years
  - 19% considering use in 3 to 5 years

- https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/

Specialty Capture/Alternative Funding Sources

What are the “Specialty”/Alternate” Funds/Sources?

Manufacturer Programs

- Free-Drug
- Copay Assistance Programs (CAPS)

Foundations

Patient Advocacy Groups

Brownbagged, Whitebagged Drugs

Importations from Canada and oversease (India, Australia)

Other?

Alternate Funding Approaches

- Carveout subset of drugs above a certain cost – for ex. $2000 a month
- Set up alternate insurance plan and charge benefit plan for the insurance
- Pay a foundation to get a member on a funding program
- Get patient placed on patient assistance program
- Import drugs from outside the US
- Classify drugs as non essential to change patient copay obligations
- Make insured member appear uninsured or under insured so that they quality for needs-based pharmacy assistance from manufacturers or charity programs
- Use proprietary software to find funding from manufacturers and foundations
- Positioned between self-insured employers and PBMs or specialty pharmacies (for extra payment, and increasing suspicion that found monies are available

- https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/industry-experts-question-alternative-funding-companies-that-carve-out-some-specialty-drugs-abuse-charities/

Players and Their Pitch

"SaveonSP will administer a change to your plan benefit design to reduce your plan participants' financial obligations for their specialty medications.

SaveOnSP is an Express Scripts Program, and Express Scripts is now a CIGNA company."

“Non-Essential Benefit” Declaration

- Patient Protection and Affordable Care Act (ACA) essential health benefit (EHB)
  - Requires individual and small group markets to cover 10 essential health benefits including ambulatory patient services, prescription drugs, and preventive and wellness services and chronic disease management.
    - https://www.cms.gov/cciio/resources/data-resources/ehb
- Specialty carveout vendors improperly designates one or more specialty medications as a “non-essential” health benefit, and therefore not subject to the ACAs EHB limits on consumers’ annual out of pocket costs
  - Vendor then charges patients copays equal to the full amount of copay assistance available through the manufacturer copay assistance program
  - AND refuses to count the medication copays toward the consumers’ annual deductible and annual out-of-pocket costs

A Growing Market Niche – saving $ for Employers

Third Party Vendors

- ImpaxRx - www.impaxrx.com (Prescription Advocates)
- PaydHealth – www.paydhealth.com (Advocacy Service)
- PayerMatrix – www.payermatrix.com (Clinical Care Management, Specialty Drug Advocacy)
- RxFree4me – www.Rxfree4me.com (Pharmacy Consulting Company)
- SHARx – www.sharxplan.com
- SaveOnSP – www.saveonSP.com (Plan Participant-Focused Cost Saving Services)
- ScriptSourcing – www.scriptsourcing.com (Saving People Money on Name Brand Medications)
- And at least 14 more……..

ImpaxRx, Boca Raton, FL

Fully insured employers receive no transparency. Hidden costs bundled in medical and pharmacy benefits.

Alternate Distribution Channels to help individuals qualify for MUM™ solutions

No More Copays for qualifying employees

Medications delivered to patient home or prescribing MD offices

Once the employer engages with ImpaxRX MUM™ the employee must participate in the process by providing all the documentation and information to ImpaxRX™ in order to use the benefits.

CA hospital, 28 employees qualified out of 370. 17 high cost specialty medications, 1 short duration. Added 2 more employees and 4 more drugs during the year $622K savings to date

PA charter school, 15 employees qualified out of 418. 11 high cost specialty medications. Added 5 more employees and 4 more drugs during the year. $696K savings to date.

PaydHealth, Dallas TX

- Empathetic Savings, Alternate Funding Solutions, Prescription Benefit, Medical Benefit
- Many Drug Manufacturer Programs to get reduced or no cost to the employee
- Team will secure funding for medication not covered under insurance plan
- **Health Plan denies drug, sends to PaydHealth (CareFactor). Letter and FAQ sent to employee, 30 days to complete applications including household size and income. Drug card used in the interim during securing funding. If approved, employee receives free drug from manufacturer (usually for 6 to 12 months). If partial funding approved, SP (Magellan) fills the script. Partial funding used as member responsibility so zero pay. If doesn't qualify, script goes back to SP and processed under the plan prescription benefit.**
- Magellan, city employees, unions, trust funds,
- "Plan requires employees to enroll in the Specialty Healthcare Advocacy Program" If you do not, Coinsurance or Out of Pocket costs will be 100% of pharmacy billed charges and not apply to annual maximum amount or deductible"
- If not eligible for identified alternate funding, case will be automatically submitted for benefit reconsideration under the Plan
- All specialty drugs paid for by plan must be distributed by _____Specialty Pharmacy

PaydHealth Select Drugs and Products℠ List 1/1/22 Page 1 https://www.neca-ibew.org/PaydHealth

Paydhealth

Select Drugs and Products℠ List

Effective January 1, 2022 - Healthcare practitioner-administered in italics

PaydHealth Select Drugs and Products℠ List 1/1/22 Page 2 https://www.neca-ibew.org/PaydHealth

PaydHealth Select Drugs and Products℠ List 1/1/22 Page 3 https://www.neca-ibew.org/PaydHealth

Paydhealth

Select Drugs and Products℠ List

Effective January 1, 2022 - Healthcare practitioner-administered in italics

IMPORTANT

This is a list of medications that changes periodically and is reviewed each calendar quarter.

To ensure you have the most current version of the Select Drugs and Products℠ List, visit your designated Paydhealth website address.

Inclusion of a medication on this list is not a guarantee of coverage. Please refer to your plan benefit documents for coverage limitations and exclusions.

Not all benefit plans include healthcare practitioner administered specialty drugs (noted in italics). For details regarding your benefits plan, contact Customer Service at the telephone number listed on your identification card.

Notice

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Paydhealth

PayerMatrix, Media, PA

Founded 2016

Express Scripts Pharmacy, SouthernScripts, EmiRx, Phoenix PBM, among others

YouTube: Union Labor Advisory Network interview

2021 first Innovations Summit winner at Purchasers Group on Health (WA)

Secures alternative funding

Collects commission of up to 30% of any savings

2019 New York City Transit Union vs Metropolitan Transportation Authority of NYC

- Both arguing the other brought PayerMatrix in to discussions, **MTA called out union boss on "specialty drug scam" and racially discriminatory (excludes drugs for chronic diseases like sickle-cell anemia),** projected savings of $50 million, but only for US citizens, not hundreds of union members not yet citizens.

One Union Benefit Changes

- Effective January 1, 2019, IPC Evergreen/PillarRx is being replaced by a new firm, Payer Matrix. Payer Matrix is able to access discounts on a larger number of specialty drugs, thereby providing more cost relief to both you and the Plan. Our goal with implementing this new vendor is that your co-pay will be entirely covered by the discount. In order to accomplish this, the new specialty drug co-payment is 100% of the discounted cost of the drug. In most case, Payer Matrix will be able to obtain alternate funding for the drug and there would be no member co-payment. If alternate funding is not available, the drug will be subject to the current tiered co-pay of $15.00 for generic, $45.00 for formulary brand, and $95.00 for non-formulary brand, up to a 30-day supply.
- Effective February 1, 2019, the prescription drug formulary managed by MagellanRx will also change. Non-specialty Brand drugs not on the MagellanRx formulary will be excluded from coverage, except in circumstances of medical necessity. Medical necessity determinations including appeals will be handled by MagellanRx and their contracted independent review organizations.
- https://ecommerce.issisystems.com/isite200/eremitimages/200/documents/SMM%20All%20Wel%20Funds%20December%202018.pdf

PayerMatrix Non-Formulary Specialty Drug List 06/01/2020 Page 1

J-Code	Drug Name	Alternate Funding
C9014	BRINEURA	Alternate Funding
J0129	ORENCIA	Alternate Funding
J0135	HUMIRA	Alternate Funding
J0178	EYLEA	Alternate Funding
J0178	HARVONI	Alternate Funding
J0221	LUMIZYME	Alternate Funding
J0256	PROLASTIN	Alternate Funding
J0364	APOKYN	Alternate Funding
J0485	NUVOJIX	Limited Funding
J0490	BENLYSTA	Alternate Funding
J0517	FASENRA	Alternate Funding
J0584	CRYSVITA	Alternate Funding
J0585	BOTOX	Alternate Funding
J0588	XEOMIN	Limited Funding
J0597	BERINERT	Alternate Funding
J0599	HAEGARDA	Limited Funding
J0599	CINRYZE	Variable Funding
J0638	ILARIS	Limited Funding
J0717	CIMZIA	Alternate Funding
J0882	ARALAST	Alternate Funding
J0882	ARANESP	Alternate Funding
J0885	EPOGEN	Alternate Funding
J0885	PROCRIT	Alternate Funding
J0888	PROCRIT	Alternate Funding
J0897	PROLIA	Alternate Funding
J0897	XGEVA	Alternate Funding
J1300	SOLIRIS	Limited Funding
J1428	EXONDYS	Alternate Funding
J1438	ENBREL	Alternate Funding
J1442	NEUPOGEN	Alternate Funding
J1459	PRIVIGEN	Limited Funding
J1559	HIZENTRA	Limited Funding
J1599	TALZENNA	Alternate Funding
J1602	SIMPONI	Alternate Funding
J1628	TREMFYA	Alternate Funding
J1645	FRAGMIN	Limited Funding
J1726	MAKENA	Alternate Funding
J1744	FIRAZYR	Variable Funding
J1745	REMICADE	Alternate Funding
J1786	CEREZYME	Variable Funding
J1830	BETASERON	Alternate Funding
J1930	SOMATULINE	Alternate Funding
J1930	SUMATULINE	Alternate Funding
J1944	ARISTADA	Alternate Funding
J2182	NUCALA	Alternate Funding
J2315	VIVITROL	Alternate Funding
J2323	TYSABRI	Alternate Funding
J2326	SPINRAZA	Alternate Funding
J2326	SPINRAZA	Variable Funding
J2350	OCREVUS	Alternate Funding
J2353	SANDOSTATIN	Alternate Funding
J2357	XOLAIR	Alternate Funding

PayerMatrix Non-Formulary Specialty Drug List 06/01/2020 Page 2

J-Code	Drug Name	Alternate Funding
J2502	SIGNIFOR	Alternate Funding
J2505	NEULASTA	Alternate Funding
J2507	KRYSTEXXA	Alternate Funding
J2786	CINQAIR	Alternate Funding
J2796	NPLATE	Limited Funding
J2940	KANUMA	Alternate Funding
J2941	GENOTROPIN	Limited Funding
J2941	HUMATROPE	Limited Funding
J2941	NORDITROPIN	Alternate Funding
J2941	NUTROPIN	Alternate Funding
J2941	OMNITROPE	Alternate Funding
J3110	FORTEO	Alternate Funding
J3111	EVENTITY	Alternate Funding
J3262	ACTEMRA	Alternate Funding
J3285	REMODULIN	Alternate Funding
J3315	TRELSTAR	Alternate Funding
J3357	STELARA	Alternate Funding
J3380	ENTYVIO	Alternate Funding
J3490	EMFLAZA	Limited Funding
J3490	LUXTURNA	Limited Funding
J3490	PREVYMIS	Limited Funding
J3490	TARGRETIN	Limited Funding
J3590	CABLIVI	Alternate Funding
J3590	ILUMYA	Alternate Funding
J3590	KEVZARA	Alternate Funding
J3590	REPATHA	Alternate Funding
J3590	SILIQ	Alternate Funding
J3590	SKYRIZI	Alternate Funding
J3590	TAKHZYRO	Alternate Funding
J3590	TYMLOS	Alternate Funding
J3590	ULTOMIRIS	Variable Funding
J3590	ZOLGENSMA	Variable Funding
J3590	COSENTYX	Alternate Funding
J3950	NIVESTYM	Alternate Funding
J7170	HEMLIBRA	Limited Funding
J7179	VONVENDI	Limited Funding
J7182	NOVOEIGHT	Limited Funding
J7185	XYNTHA	Limited Funding
J7186	ALPHANATE	Limited Funding
J7189	NOVOSEVEN	Limited Funding
J7190	HEMOFIL	Limited Funding
J7192	ADVATE	Limited Funding
J7192	KOGENATE	Limited Funding
J7192	RECOMBINATE	Limited Funding
J7193	ALPHANINE	Alternate Funding
J7193	MONONINE	Limited Funding
J7195	BENEFIX	Limited Funding
J7195	IXINITY	Limited Funding
J7198	FEIBA	Limited Funding
J7200	RIXUBIS	Limited Funding
J7201	ALPROLIX	Limited Funding
J7202	IDELVION	Limited Funding

PayerMatrix Non-Formulary Specialty Drug List 06/01/2020 Page 3

J-Code	Drug Name	Alternate Funding
J7207	ADYNOVATE	Limited Funding
J7208	JIVI	Limited Funding
J7209	NUWIQ	Alternate Funding
J7210	AFSTYLA	Limited Funding
J7211	KOVALTRY	Limited Funding
J7312	OZURDEX	Alternate Funding
J7313	ILUVIEN	Alternate Funding
J7502	SANDIMMUNE	Alternate Funding
J8499	EPIDIOLEX	Limited Funding
J8499	GALAFOLD	Variable Funding
J8655	AKYNZEO	Alternate Funding
J8655	DOVATO	Alternate Funding
J8999	COTELLIC	Alternate Funding
J8999	DAURISMO	Alternate Funding
J8999	ERIVEDGE	Alternate Funding
J8999	IBRANCE	Alternate Funding
J8999	NEXAVAR	Alternate Funding
J8999	RUBRACA	Limited Funding
J8999	TARCEVA	Limited Funding
J8999	TIBSOVO	Limited Funding
J8999	XOSPATA	Limited Funding
J8999	ZOLINZA	Alternate Funding
J9022	TECENTRIQ	Variable Funding
J9035	AVASTIN	Limited Funding
J9041	VELCADE	Alternate Funding
J9119	LIBTAYO	Limited Funding
J9145	DARZALEX	Alternate Funding
J9176	EMPLICITI	Limited Funding
J9202	ZOLADEX	Limited Funding
J9228	YERVOY	Alternate Funding
J9264	ABRAXANE	Alternate Funding
J9271	KEYTRUDA	Alternate Funding
J9299	OPDIVO	Alternate Funding
J9303	VECTIBIX	Alternate Funding
J9306	PERJETA	Alternate Funding
J9312	RITUXAN	Alternate Funding
J9325	IMLYGIC	Alternate Funding
J9330	TORISEL	Alternate Funding
J9355	HERCEPTIN	Alternate Funding
J9400	ZALTRAP	Limited Funding
Q2040	KYMRIAH	Alternate Funding
Q2041	YESCARTA	Alternate Funding
Q5104	RENFLEXIS	Alternate Funding
Q5105	RETACRIT	Alternate Funding

RxFree4Me, Detroit, MI area

- Save up to 75% of cost of medications.
- Drugs dispensed domestically and from Canada
- Savings becomes a $0 copay to employees
- Patient holds the prescription from the MD and passes it on for filling
- Terms and Conditions reference shipping delays, delivery must be signed for, “prescription has not been altered in any way nor has it been filled prior to submission to RxFree4Me”, patient must contact physician if they have any unexpected side effects from medications ordered from RxFree4Me

SHARx, St. Louis, MO

- Targets all high cost medications that are driving up employer health care costs
- Members often get their drugs free, and those that are not free are typically at cash pharmacies with pricing 75% to 90% lower than local pharmacies
- CEO had child with rare disease and found resource that paid for all of the financial costs…so founded SHARx
- Works with multiple PBMs, fulfills prescriptions through non-traditional channels
- Fee paid per employee per month
- Procures high cost maintenance, specialty meds, infusion therapies, and orphan disease drugs directly from the manufacturer or through mail order pharmacy partners (i.e. Humira, Cosentryx, or Spinraza)
- Lots of YouTube videos at https://www.sharxplan.com/group-faqs/
- Caution: medications can take 2 to 4 weeks or 5 to 7 weeks depending on whether they are shipped domestically, from Canada, or from overseas

What does SHARx call High Cost Drugs?

- Any medication that costs more than $200 for a 30-day supply would be considered high-cost. These would include: Insulin (all types), Abilify, Actemra, Advair, Androgrel, Atripla, Breo, Brilinta, budesonide, Bydureon, Canasa, Celebrex, Cialis, Concerta, Crestor, Cymbalta, Dexilant, Effient, Eliquis, Elmiron, Enbrel, Flovent HFA, Gilenya, Glatopa, Glyxambi, Humira, Invokana, Janumet, Januvia, Latuda, Lipitor, Lyrica, Multaq, Onfi, Plavix, Premarin, Prolia, Remicade, Restasis, Seroquel, Singulair, Spiriva, Stelara, Toujeo, Viagra, Victoza, Vyvanse, Welchol, Xaralto, Xolair, and MANY, MANY More!!

SHARx Results

Large Employers

- 2077 lives, $4.2 million savings
- 1,260 lives, $1.3 million savings

Mid Size Employers

- 237 lives, $238K savings
- 157 lives, $227K savings

Average Employer savings is $1,100 per enrolled employee. Average employee savings is $800

ScriptSourcing, Bonita Springs, FL, Baltimore, MD

- Search function for medications they can source
- Enroll in $0 Rx copay programs
- Rather than use PBM, use ScriptSourcing to direct source specialty medications at typical savings of 50 – 75%
- Paid on % of savings
- Home Health care client in PA with 130 enrolled members saved $608K in 4 years. Refills mailed direct to member homes, 85% first year savings
- Manufacturer client in CA with 350 employees. Within 4 months, 42 prescriptions saved $192K. 67% savings and members had $0 copay
- Private college in PA with 721 enrolled members. Within 6 months, $120K savings. By end of year, $177K savings. Members had $0 copay

SaveOnSP, New York State

- SaveOnSP is marketed by Express Scripts and Express Scripts is now a CIGNA company
- “non-essential health benefits copay assistance solution”
- Identifies select drugs as non-essential health benefits, so they can be carved out, enabling maximum savings and reducing plan and member costs. The Affordable Care Act (ACA) Essential Health Benefit requirements don’t cover drugs declared to be “non-essential health benefits”, so those drugs can be carved out of a health benefit plan.
- If patients needing those carved out drugs do not enroll in and use SaveOnSP, filling their prescriptions exclusively from Express Script’s Accredo SP, they can require patients to pay the full amount of the value of the manufacturer’s copayment program. If a copayment program value is $20,000, not enrolling in SaveOnSP could cost a patient the full $20,000 without regard to plan OOP maximums.
- Elements of a copay maximizer program – when patient out of pocket drug costs are $0, patients still owe their full deductible for other expenses
- Receives 25% of savings as a fee
- Founded in 2015

Lawsuit against SaveOnSP

Brought by Johnson & Johnson in 2022 in New Jersey

SaveOnSP has moved to dismiss

Aimed Alliance, Triage Cancer, the HIV and Hepatitis Policy Institute, The Coalition of State Rhematology Organizations, and the AIDS Institute, the National Oncology State Network and the Connecticut Oncology Association have filed an Amici Curiae Brief August 15, 2022 in opposition to SaveOnSP's motion to dismiss. https://aimedalliance.org/aimed-alliance-submits-amicus-brief-in-lawsuit-to-enjoin-non-ehb-program/

- https://endpts.com/jj-suing-company-over-alleged-abuse-of-its-cost-assistance-program/

Adverse Consequences: Real and Potential

Real Experience in Missouri

- We are dealing with everything from these plans excluding high dollar oncology drugs and forcing our hand into applying for drug assistance, refusing to pay contracted rates until copay assistance is exhausted along with the white bagging and step therapy requirements. In turn these requirements have caused unnecessary stress to our patients at times.

- It is most definitely a growing problem.

View from Rheumatology

- For employers, the cost of health insurance is second only to their payroll expense. Per person spending in employer plans grew by 22% between 2015 and 2019. This outpaced inflation and economic growth.
- Because employers who self-fund the health care for their employees are increasingly desperate to save money, they will often agree to plans that are less expensive but offer suboptimal care, particularly for patients with chronic diseases requiring expensive medicines.
- Many employers are not fully informed of the ramifications of these policies, so the Coalition of State Rheumatology Organizations is creating an educational employer tool kit that not only highlights the importance of disease control for their employees with rheumatic conditions but also outlines the pitfalls and misinformation that may be given to them by the insurance companies, PBMs, and other third parties that administer their health plan.
- Utilization management legislation, which has passed in many states, can be easily found on CSRO's map tool https://csro.info/non_cms_pages/legislationin-your-state.php

- Forced ‘white bagging’ in self-funded plans
- TPAs then attempt to obtain the medications from the manufacturers, foundations, compounding pharmacies, and even other countries for free or highly discounted prices. Even if obtained at no cost, the TPA will charge the employer a percentage of the list price or fee for obtaining it.
- The legality of this practice is questionable when these companies pretend to be the patient when applying for the assistance or present compounded medication as coming from the manufacturer, or if the TPA obtains the medication from outside the country.

- “Employers’ self-funded health plans can leave rheumatology patients vulnerable”, Madelaine Feldman, MD, MD edge Rheumatology, September 20, 2022

Good or Bad is a Point of View

Employer/Employee

- Specialty funding available for the seeking
- $0 drug cost to employer for high-cost specialty/orphan drugs
- $0 copays
- Willing to pay 25- 30% to get hundreds of thousands or millions in savings
- Presented at "Best of the Best' employer business group meetings for innovation
- Savings from shipped drugs from Canada and overseas is an asset (50% - 75%)
- Blind eye being turned to importation due to savings potential (municipalities, states, employers)

Physician/Manufacturer/Foundations/CAPs

- Specialty funding is limited and reserved for patients in need
- Employers making a financial decision to carve out specific drugs and diseases based upon cost does not constitute the definition of patients in need
- Draining "soup kitchens" equivalent
- Importation of drugs from Canada or overseas for quantities greater than individual use is against federal law
- Physicians still held liable for medical complications even if they have no control over sourcing of drug

Legal Challenges?

Patient Harm

- Direct from unpedigreed drugs
- Indirect by reduced access to needed drugs because programs were drained

Treatment Delays

Confusion

Coercion to enroll

Risk/Harm/Legality of Drug Importation

Johnson & Johnson takes legal action

- MAY 05, 2022
- Johnson & Johnson sues benefits company for allegedly overusing drug cost assistance program
- J&J alleges that SaveOnSP intentionally circumvents the Affordable Care Act's patient protections.
- Buffalo, New York-based SaveOnSP, which is run by PWGA Pension & Health Plans, describes itself on its website as "a service that negotiates prices for specialty drugs and, in exchange for the exclusive right to do so, guarantees that the recipients of those covered prescriptions will pay $0."
- In the civil lawsuit filed in federal court in New Jersey, J&J said it overpaid in copay assistance by at least $100 million due to the services provided by SaveOnSP. This, said J&J, is due to contract interference and deceptive trade practices by the company.
- SaveOnSP charges the payer "25% of the savings that's achieved."
- https://www.healthcarefinancenews.com/news/johnson-johnson-sues-benefits-company-allegedly-overusing-drug-cost-assistance-program

Amici Curiai Brief

Amici Curiae Brief August 15, 2022 in opposition to SaveOnSP's motion to dismiss, on grounds that SaveonSP:

- Conduct deceives, influences, and harms consumers
- Conduct deceives health care consumers
  - Causes pharmacies to tell consumers that their medications are not covered by insurance
  - Informs consumers that, under its program, there is no copay
  - Does not disclose that, under its program, copay assistance is not counted toward consumers' deductible or annual out-of-pocket limit
  - Does not disclose that it places its interests before the interests of consumers
- Conduct harms consumers
  - Conduct delays health care access and causes consumers to pay more for their health care
  - Conduct causes consumers to forego health care products and services
- Conduct has national health policy implications
  - Mischaracterizes the purposes of Copay Assistance Programs (CAPS)
  - Threatens patient's health stability by jeopardizing their ability to rely on CAPS
  - Threatens patient and public health by serving as a roadmap for eroding Employee Health Benefit (EHB) protections
  - Increases overall health care costs by inflating the cost of prescription medications

- https://aimedalliance.org/aimed-alliance-submits-amicus-brief-in-lawsuit-to-enjoin-non-ehb-program/

Plan of Action for Change

Some Impact Already Being Felt

- Article and written warning from premara – Now Removed from Online
- SaveOnSP Program Impacted by Drug Manufacturer Changes
- https://www.premera.com › news › large-group › saveo...
- Jan 12, 2023 — Premera recently became aware of changes made to drug manufacturer coupon Terms and Conditions that impact copay maximizer programs, such as ...
- Jan 12, 2023 — At this time **SaveOnSP** is still closed to new sales. Program Changes. **Premera** recently became aware of changes made to drug manufacturer coupon ...

Awareness, Document, Education, Challenge

Awareness

- Watch for specialty carveouts for employed patients
- Track employer for all patients to facilitate trend analysis

Document

- Document disease, drugs, employers
- Document adverse consequences for patients as they are forced through the process, rates of substitution, funding sources, medication sources, frequency of recoverage under benefit plan if patient not eligible, frequency of patient forgoing needed treatment due to the process or communications, track communications regarding the program sent to prescribing physicians, track impact on patients if physicians refuses whitebagged drugs

Education

- Align with state societies, National Oncology State Network, Aimed Alliance and others to develop talking points, key issues, to be shared with employers of affected employees: unanticipated adverse consequences, legal and risk challenges, safety concerns, continuity of care issues, etc.

Challenge

- Serve as an ambassador to local business groups, unions, employee groups, accountable care organizations, individual employers, to warn of the adverse consequences to benefit members, employers, patients in need, foundations, CAPS, and oncology providers from these programs

Key Constituencies for Impact

- State Insurance Commissions
- State Consumer Advocacy Departments
- Patient Advocacy Organizations (Specialties, Cancer or Disease Specific)
- Employer of Affected Members (May not even know the program is part of their benefit package)

If we see something, say something

These are not specialty funding sources with pots of free money for the taking

They are raised funds designated for patients in need

Selectively un-insuring employed insured patients for specific diseases, orphan diseases, solely based upon the costs of treatment is reprehensible, but may be naïve

Third parties engaged in these “sales” to employers are not telling them the whole story. Employers also are being tempted and deceived by these entities and deserve to know the full implications.

We cannot be Naïve either

- Medical and pharmaceutical costs are sky-high
- For any employer, less than 5% of their insured members could incur unsustainable cost burdens.
- 1.2% of insured members can be responsible for 1/3 of employer medical costs
- Programs that shift savings into $0 member out of pocket costs may increase compliance and adherence
- What would you do as an employer if these companies pitched these savings for your own benefit plan?
- What is the tipping point for penetration of these programs to drain specialty funding sources? When or can we document needy patients being harmed or losing access to care? Countering such programs must be grounded in facts, not emotions.

Thank You, and Good Luck

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