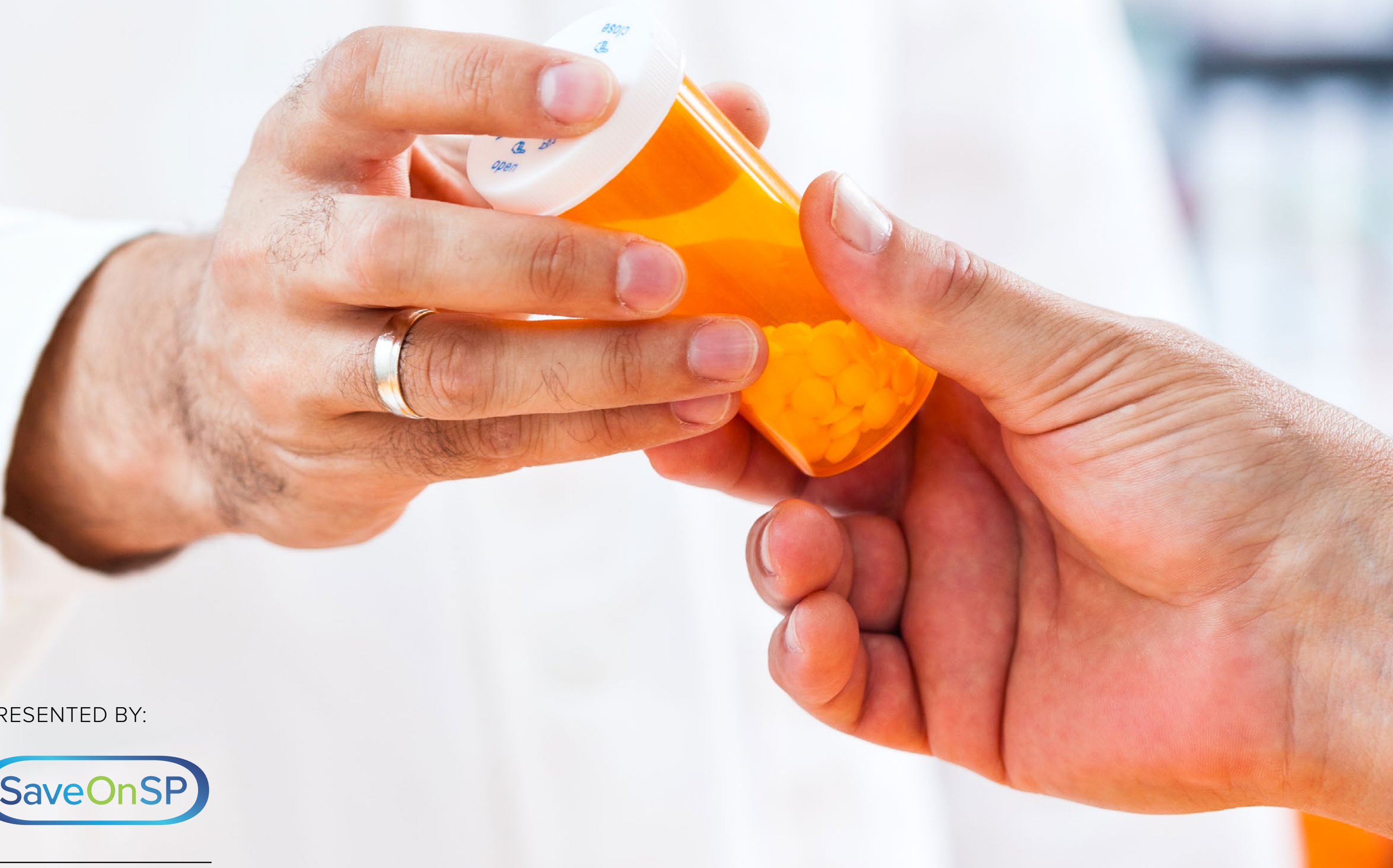
WHITEPAPER

Copay Maximizers Vs. Accumulator Adjustments:

Navigating key differences for an optimized solution

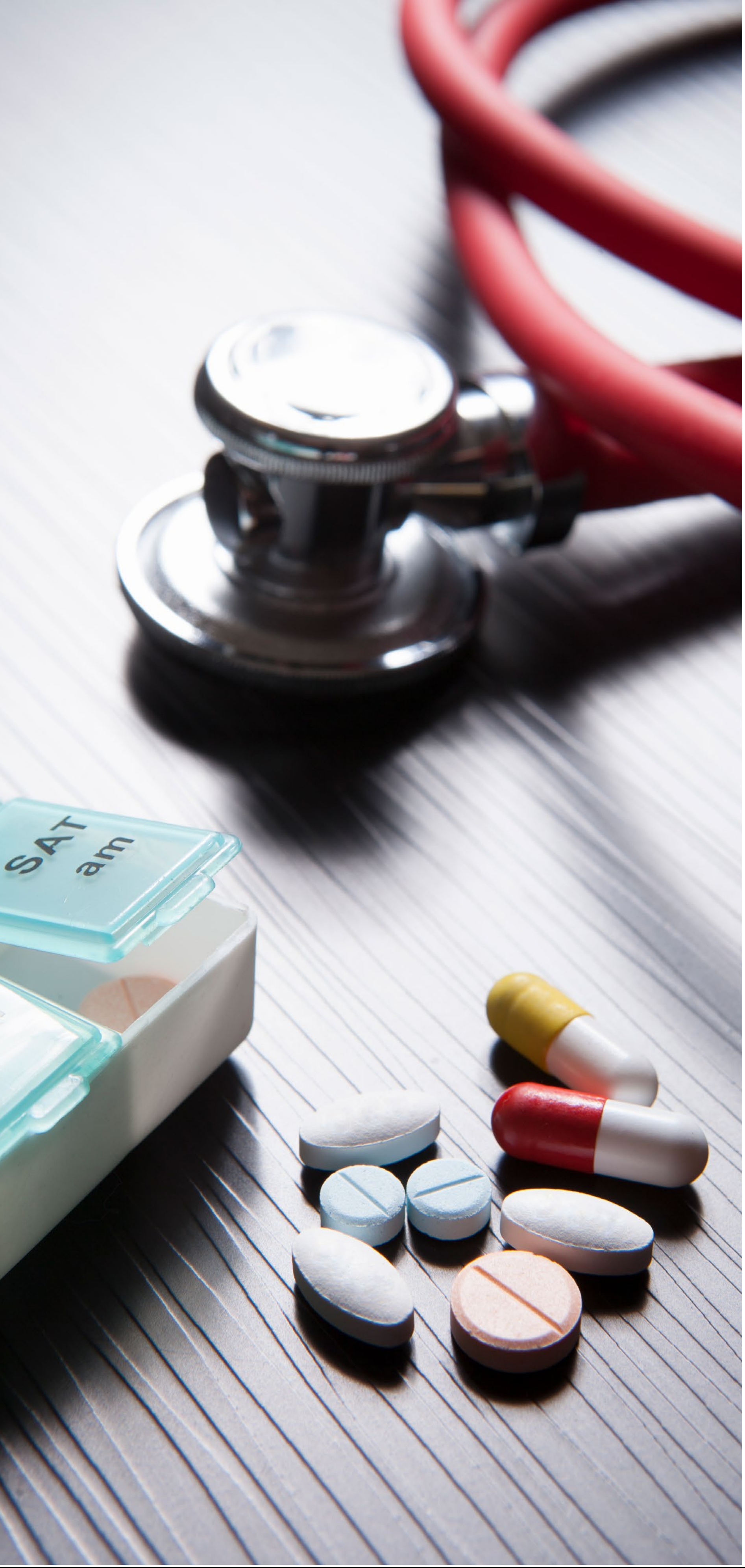


PRESENTED BY:

SaveOnSP

PUBLISHED BY:

FIERCE Pharma

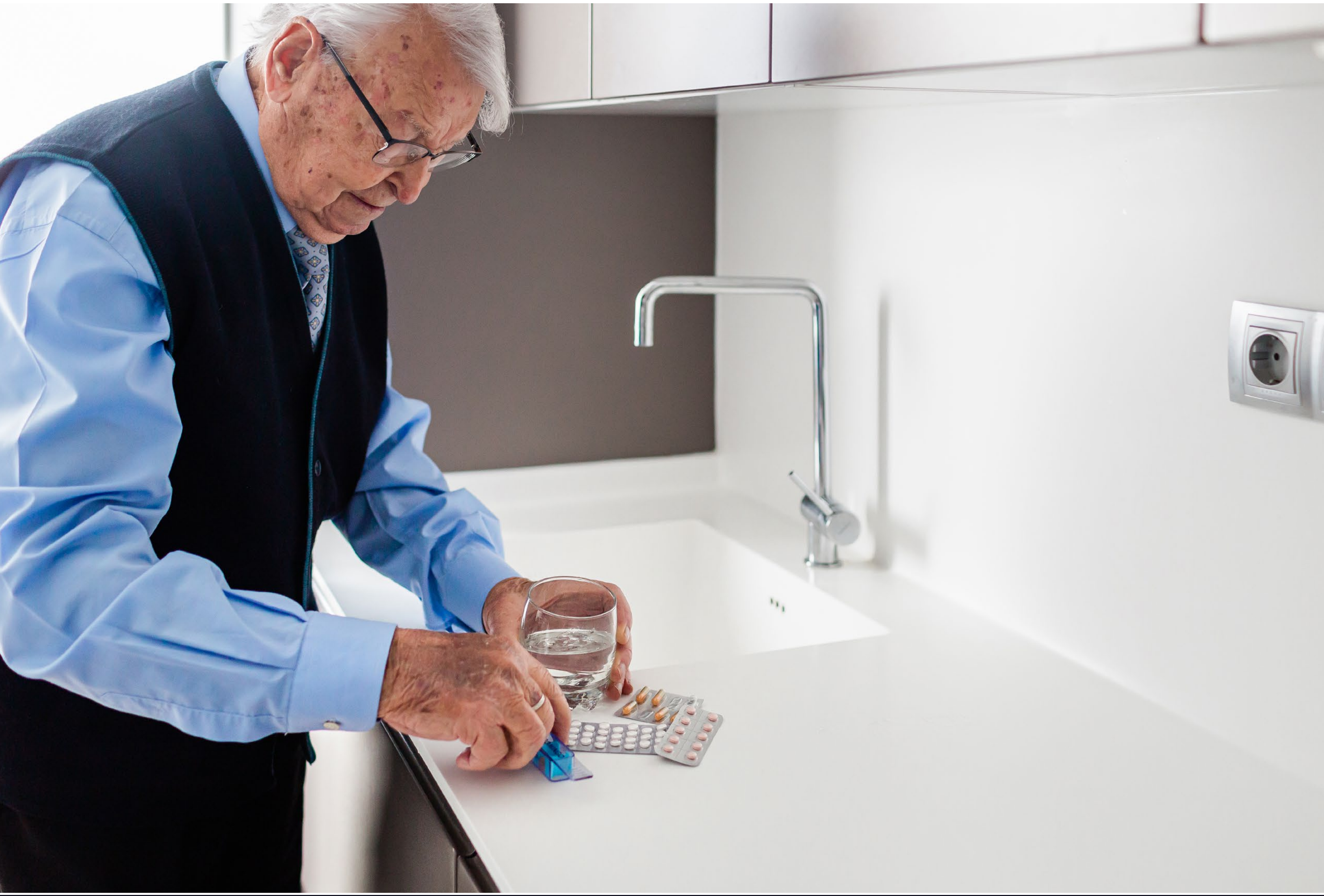


CONTENTS

INTRODUCTION

The dramatic rise in specialty medications has made new and valuable treatment options available for patients living with complex, chronic conditions like cancer, rheumatoid arthritis, multiple sclerosis, and rare diseases. However, there has been a significant economic impact due to the growing specialty medication market and the high costs associated to specialty medications. Paired with pharma's market commercialization strategies, employers, insurers, and patients are struggling to afford these therapies.

In this overview, we will discuss the continually expanding specialty market, highlight certain cost drivers and market dynamics, and provide insight on solutions for managing the cost of specialty medications. We will highlight the key differences between an accumulator adjustment program and a copay maximizer program, outlining key differentiating features of the SaveOnSP solution.



VALUE OF SPECIALTY MEDICATIONS

Advances in the development of specialty medications can often provide transformational and life-altering therapies for patients. The market for specialty medications continues to grow, representing over 53 percent of the total annual drug spend with a large pipeline of new products that will continue to put pressure on the sustainability of our healthcare system. Traditionally, drug pricing practices and commercialization strategies have provided manufacturers with market share growth by offering an aggressive financial patient-support model, removing the incentive for patients to switch to lower cost alternatives that may be available on the market. The Institute for Clinical and Economic Review (ICER) is a drug pricing watchdog that completes cost effectiveness evaluations and has identified that pricing practices for certain specialty products often do not coincide with patient value based on the clinical evidence. Much of the financial burden of covering these medications lies with employers, who are tasked with navigating rising costs while ensuring competitive benefits for their work force.

Over a 24-month period (eight quarters), adalimumab's (better known as Humira) Wholesales Acquisition Cost (WAC) increased by approximately 19%. Considering the average volume sold in 2017-2018, the price change resulted in an estimated increase in drug spending of $1.86 billion. After a review of evidence from the manufacturer, ICER concluded that: "adalimumab had a price increase unsupported by new clinical evidence.[1]

1 *ICER Unsupported Price Increase 2019 Assessment (http://icerorg.wpengine.com/wp-content/uploads/2020/10/ICER_UPI_Final_Report_and_Assessment_110619.pdf)*

THE BIRTH OF COPAY ASSISTANCE PROGRAMS AND THEIR IMPACT ON HEALTHCARE SPENDING

A copay assistance program, a type of patient support, allows a drug manufacturer to pay all or some of a patient's prescription drug cost for that manufacturer's drug, usually in the form of a coupon or debit card. This financial incentive for the patient has caused brand loyalty and resulted in these drugs bypassing the patient's benefit design. Patients are then sheltered from alternative, lower-cost medications and unsustainable drug price increases with the cost being shouldered entirely by the plan sponsor.

Highlights from published research include:

- Drugs without copay assistance experience real price growth of 7-8 percent per year, while drugs with copay assistance experience price growth of 12-13 percent annually. Research has shown that the introduction of copay assistance programs can correspond with up to a $120 million increase in drug spending.[2]
- Among the highest total drug expenditures by commercial insurers, the median drug wholesale list price (as defined by Average Wholesale Price) increased by 129 percent from 2010 to 2016. Concurrently, median patient out-of-pocket costs increased by 53 percent, while median insurance payments after rebates and discounts increased by 64 percent.[3]
- Copay assistance programs help sustain drug-specific utilization at the cost of the plan while growing the drug's market share. Nearly 70 percent of the 132 highest-spend branded drugs in 2014 offered copay assistance, and in recent years, the percentage of assistance programs specific to specialty medications has risen to over 90 percent.[4]
- A 2016 National Bureau of Economic Research study found coupons "increase branded sales by 60 percent, entirely by reducing the sales of bioequivalent generics." Manufacturers build the cost of copay assistance into their pricing strategies and use them to maximize brand loyalty and bolster sales.[5]
- From 2000 to 2018, the gross profit margin of 35 large pharmaceutical companies was significantly greater (up to 40 percent greater) than 60 percent of the S&P 500 public companies.

Health plans and employers have expressed concerns surrounding this practice as it allows a manufacturer subsidy to accumulate towards funding other healthcare expenses and creates an unequal benefit for the remaining employees who are not receiving financial assistance from a drug manufacturer. With the growing specialty drug pipeline and current products that can cost over $150,000 annually per patient, employers and plan sponsors are left to face the consequences of these unsustainable price increases and high-cost medications. It has become critical to identify innovative approaches that successfully balance the employer's need for value with the patient's need for affordability and access to treatment.

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2 *https://www.hbs.edu/ris/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf*

3 *Yang EJ, Galan E, Thombley R, et al. Changes in Drug List Prices and Amounts Paid by Patients and Insurers. JAMA Netw Open. 2020;3(12):e2028510. doi:10.1001/jamanetworkopen.2020.28510*

4 *Van Nuys K, Joyce G, Ribero R, Goldman D. Prescription drug copayment coupon landscape. Leonard D. Schaeffer Center for Health Policy & Economics website. healthpolicy.usc.edu/research/prescription-drugcopayment-coupon-landscape. Published February 7, 2018)*

5 *https://cdn.ymaws.com/www.tahp.org/resource/collection/F53C4497-8661-4A9B-A56D-DDC171374C4F/Explaining_Manufacturer_Coupons_and_Assistance.pdf)*

SOLUTIONS TO THE PROBLEM-ACCUMULATOR ADJUSTMENT AND COPAY MAXIMIZER PROGRAMS

One solution to address high drug costs is through an accumulator adjustment program. Traditionally, a healthcare benefit design is comprised of member deductibles and copayments or coinsurance, which culminates to an annual member-spend limit defined as an out of pocket maximum. Accumulator adjustment programs are offered by many insurance companies and Pharmacy Benefit Managers (PBMs) as a tool for employers to create equal cost-share requirements for all employees related to their benefit plan design. An accumulator adjustment program is designed to prevent manufacturer copay assistance from counting towards a patient's deductible and out of pocket maximum while still allowing these dollars to support the patient's medication cost. Accumulator adjustment programs have been perceived by patient advocates as unfair since many patients have previously been able to meet their plan cost requirements solely with the manufacturer assistance dollars available for their medication. With an accumulator adjustment program, members will remain responsible for their plan copay, co-insurance and deductible once copay assistance has been exhausted, as well as for any other healthcare-related expenses as required by their benefit design.

A consequence seen with accumulator adjustment programs has been the negative impact to a patient's treatment medication adherence and persistence when manufacturer subsidized funds run out and the patient remains responsible for their health benefit plan-required cost share. Adherence is the proportion of medication taken over a specific interval, and persistence is the continued use of a prescribed treatment. If a patient stops taking their medication or takes it intermittently based on affordability, it could lead to an increase in morbidity and mortality.[6] Successful treatment of these specialty conditions is dependent on adherence to these high-cost medications. Research has shown accumulator adjustment programs are associated with lower adherence, lower persistence, and higher risk of treatment discontinuation.[7] Accumulator adjustment programs have received tremendous scrutiny for the negative patient experience, which has resulted in many state legislatures banning use of them.

6 *Bonafede MMK, McMorrow D, Proudfoot C, Shinde S, Kuznik A, Chen CI. Treatment Persistence and Healthcare Costs Among Patients with Rheumatoid Arthritis After a Change in Targeted Therapy. American Health Drug Benefits. 2018 Jun;11(4):192-202.*

7 *Bruce W. Sherman, MD; Andrew J. Epstein, PhD; Brian Meissner, PharmD, PhD; and Manish Mittal, PhD. Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence. Am J Manag Care. 2019;25(7):335-340*

Recognizing the adverse patient impact of an accumulator adjustment program and the financial responsibility that remains with the patient once copay assistance funds are exhausted, copay maximizer programs emerged as an alternative solution. While accumulator adjustment and copay maximizer programs are mentioned in the same breath by those in the industry, there are key differences between these solutions. It's important to understand that unlike an accumulator adjustment program, copay maximizers function differently and offer a unique patient experience. However, market confusion and lack of insight on these solutions have led to a halo effect, inappropriately interchanging these programs.

The copay maximizer program offered by SaveOnSP allows employer sponsored plans to align their employees' copayment/coinsurance obligations to the annual dollar amount available by the manufacturer, which provides a predictable and affordable benefit cost-share throughout the plan year. By "maximizing" these available funds, costs for employers, insurers, and patients are reduced.

As with accumulator adjustment programs, copay assistance for the SaveOnSP copay maximizer program does not apply to the patient's shared medical and pharmacy deductible or out of pocket. By preventing manufacturer dollars from subsidizing the shared medical and pharmacy deductible or out of pocket, employers and plan sponsors create an equal benefit across their population while providing improved visibility into the true costs of specialty drugs.

SaveOnSP manages the program by partnering with the plan's in-network specialty pharmacy and facilitating enrollment into the applicable manufacturer's copay assistance program. This coordination allows plan sponsors to estimate the cost of benefits over the year. Importantly, SaveOnSP is designed to comply with the Affordable Care Act (ACA) standards while ensuring that benefit design changes apply to select specialty drugs only with no impact to the plan's benefit design for non-specialty drugs.

By "maximizing" the available funds, costs for employers, insurers, and patients are reduced.

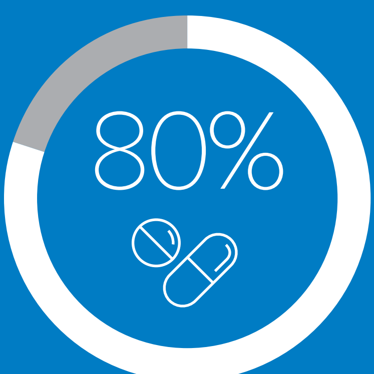
THE IMPORTANCE OF ACA COMPLIANCE WHEN EVALUATING SOLUTIONS

The Affordable Care Act (ACA) established new standards for healthcare access when Congress enacted the law in March 2010. As of January 2014, non-grandfathered, fully insured plans in the individual and small group markets and those in exchanges are required to be compliant with the ACA essential health benefit coverage requirement across ten separate categories. One of these categories is prescription drugs, where essential coverage is outlined for each drug class and category by defining a minimum number of products that must be included in coverage for that class and category. Any drug covered by a plan sponsor that exceeds the minimum required is defined by the Department of Health and Human Services as a "non-essential health benefit." It's important to note that the designation of "non-essential" does not mean these drugs are not critical, life-sustaining or life-improving for patients, but they offer plans the ability to set up customized copays and these drugs can be excluded from the deductible and out-of-pocket maximum accumulation. Due to this regulation, it is important for plans to have a solution that is compliant with the ACA requirements for prescription drug coverage since the penalties can have implications from Department of Labor, Treasury, and Department of Health and Human Services.

SaveOnSP has designed a program that incorporates up to date ACA regulatory requirements while allowing benefit design modifications focused on delivering optimized health outcomes. Unlike accumulator adjustment programs, SaveOnSP's goal is to ensure patients can overcome financial barriers while driving improved adherence and persistence to their treatment. Data from patients supported by SaveOnSP demonstrates that adherence on chronic specialty therapies across autoimmune, cancer, multiple sclerosis, and rare disease was maintained above 80 percent, which is a stark contrast to the outcomes associated with accumulator adjustment programs. In fact, according to a study in the American Journal of Managed care (July 2019), ten months after an accumulator adjustment program was applied to autoimmune specialty drugs, HSA patients had 233 fewer autoimmune drug fills per 1000 patients, 20 percentage points higher treatment discontinuation, and 12 percentage points lower PDC.[8]

In contrast, interventions by SaveOnSP resulted in an 11 percent improvement in members returning to treatment who had previously discontinued therapy when compared to the non-intervention group. By working with the employer, SaveOnSP facilitates enrollment in manufacturer copay assistance that would otherwise be confusing and difficult to navigate for their employees, helping both employee and employer reduce costs while keeping the employees on therapy.

8 *Bruce W. Sherman, MD, Andrew J. Epstein, PhD, Brian Meissner, PharmD, PhD, Manish Mittal, PhD* The American Journal of Managed Care, *July 2019, Volume 25, Issue 7*



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SUMMARY

As of September 2021, of the 37 new drugs approved by the FDA, only seven of them were non-specialty, demonstrating how rapidly the specialty pharma industry is growing. Employers need to familiarize themselves with the pharmaceutical pipeline and coordinate with their pharmacy benefits manager and health plan representatives to implement the best possible drug coverage to drive plan savings without negatively impacting patient adherence.

With a growing specialty pipeline and continually increasing specialty drug costs, it is critical that employers, brokers, and consultants evaluate specialty management solutions that won't sacrifice clinical outcomes or regulatory compliance for cost containment. Employers and benefit managers need to leverage ACA-compliant solutions that maximize savings and ensure sustainable health care premiums for all employees. It is important that plan sponsors understand the risks and rewards of available solutions while working to keep benefits affordable and sustainable for all stakeholders.

To learn more about SaveOnSP please contact your local healthcare benefits advisor.

"Pharmaceutical billing and claims are already complicated. With specialty medications and subsidized funding, it's even more daunting and near impossible to navigate. I manage medications for my stepfather and it's a bi-weekly task to check all his prescriptions and the funding left for each of them. I couldn't imagine having to do this; your service is a great benefit"

– **SaveOnSP Customer, Large Employer**

SaveOnSP, LLC was founded by and is comprised of experts in the healthcare and pharmaceutical industry. Their mission is to guide patients and plan sponsors in helping to make specialty medications more affordable. With the first non-essential health benefit copay assistance solution, SaveOnSP helps plans drive significant savings on high-cost, high-volume specialty drugs.