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## **Rx newsletter**

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# **Market trends**

## Can NADAC pricing save employers at the pharmacy?

### What is NADAC pricing?

The National Average Drug Acquisition Cost (NADAC) is intended to be the national average of the prices at which pharmacies purchase a prescription drug from manufacturers or wholesalers.

NADAC is designed to "create a national benchmark that is reflective of the prices paid by the retail community pharmacies." <sup>2</sup> The NADAC rate is defined by "drug grouping, drug category, and pharmacy type calculated as the average of the per unit cost observations." <sup>2</sup> Simply put, it is the average of drug acquisition cost submitted by retail pharmacies.

The NADAC for prescription and over-the-counter covered outpatient drugs is reported at the 11-digit National Drug Code (NDC) level.

#### Who uses NADAC?

Currently, NADAC pricing is primarily used by Medicaid for outpatient drugs. The NADAC and comparison data are updated weekly. Each month new data is posted at Medicaid.gov based on the prior months Retail Price Survey.

## What is the difference between NADAC and AWP pricing?

The AWP, or average wholesale price, is a pharmaceutical term that describes the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers. AWP "has become an important prescription drug pricing benchmark for payers throughout the health care industry." <sup>1</sup>

Payments are typically based around AWP. For example, many state Medicaid agencies utilized published drug pricing benchmarks like AWP in the past "as a primary mechanism to determine payment for drug ingredient costs." <sup>2</sup> However, AWP is not an accurate reflection of actual market prices for drugs because it is derived from selfreported drug manufacturer data. Moreover, this benchmark has faced a lot of criticism, scrutiny, and litigation because of concerns that many AWPs are artificially inflated. <sup>2</sup>

Since 2002, AWP has been under scrutiny and the subject of investigations, litigation, and legislative proposals. In September of 2011, a major publisher of pharmacy data discontinued its publication of AWP, which "heightened the need for an alternative data source for states to use when setting drug ingredient costs."<sup>2</sup>

As more states begin to adjust their legislature to include NADAC pricing outside of just Medicaid, some may begin to see lower costs associated with their pharmacy medications.

#### Sources:

1. "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?", National Library of Medicine, accessed May, 2, 2022, https://www.ncbi.nlm.nih.gov 2. "Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs", Centers for Medicare & Medicaid Services, accessed May 2, 2022, https://www.medicaid.gov/nadacmethodology 3. "Pharmacy Pricing", Medicaid.gov, accessed May 2, 2022, https://www.medicaid.gov/medicaid/prescription-drugs/ pharmacy-pricing



# Pharmacy 101

## **PBM contracts: Carve-In vs. Carve-Out**

### What does Carve-In and Carve-Out Reference?

When referencing "Carve-In" or "Carve-Out," we are talking about how the PBM contract is set up. A Carve-In contract is when the medical vendor also acts as the pharmacy vendor. A Carve-Out contract is when the medical vendor is separate from the pharmacy vendor.

#### **Carve-In**

A Carve-In contract is ideal for small, fully-insured plans and at times mandated for small, selfinsured clients. For example, Cigna, Anthem, and UHC all have rules on if carve-outs will be allowed under certain employee or member size segments like 500 employees.

#### **Advantages**

- Having both medical and pharmacy with one vendor can make operations easier to manage
- Coordination of care between medical and pharmacy benefits may improve
- Stop loss insurance coordination is easier for administration

#### Disadvantages

- · Little flexibility with plan design setup
- Combined medical and pharmacy does not provide contract transparency
- Rebates retained or partially retained by vendor
- Claims data experience is limited which provides little clarity and uncertainty into the performance of the Carve-In model.
- Audit rights are limited
- The contract typically includes penalty fees if the employer wants to change to a carve-out in the future

#### **Carve-Out**

A Carve-Out contract is a contract in which the medical vendor is separate from the pharmacy vendor. These clients are self-funded and tend to have more flexibility and contract clarity. Although, not all PBM contracts have the same level of detail and not all have the guaranteed financial contract terms and conditions.

#### **Advantages**

- Flexible plan design and clinical programs that can help reduce costs
- Transparency for both pricing and rebates guarantees
- Plan customization and control of data.
- Contract clarity.
- Plan sponsor has audit rights to review:
  - Claims, rebates, pricing, operations

#### Disadvantages

- Pharmacy is now separate from medical which adds an additional vendor and put an administrative strain on the plan sponsor
- If pharmacy and medical integrators need to be combined the vendors must collaborate together
- Most employers have a need to purchase stoploss insurance to protect themselves against catastrophic losses

Employers should always consider the advantages and disadvantages of both a carve-in and carveout contract and work with their insurance counterparts to determine the right fit.

#### Sources:

 Pharmacy Carve-in vs Care-out: CalBrokerMag.com accessed June 3, 2022. https://www.calbrokermag.com/in-this-issue/ pharmacy-carve-in-vs-carve-out/
Healthcare Costs Rising: Why Carving Out Pharmacy Benefits is Worth Considering: HRExecutive.com accessed, June 3 2022.

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# **Disease Spotlight**

## **Age-Related Macular Degeneration in America**

According to the NIH, 2-3 million Americans are suffering from Age-Related Macular Degeneration

Age-related Macular Degeneration (AMD) is "the leading cause of vision loss and blindness for Americans aged 65 years and older."

## What is Age-Related Macular Degeneration (AMD)?

Age-Related Macular Degeneration is an "eye disease that can blur your central vision. It happens when aging causes damage to the macula – the part of the eye that controls sharp, straight ahead vision."

AMD does not cause "complete blindness, but losing your central vision can make it harder to see faces, read, drive, or do close-up work like cooking or fixing things around the house."

• The number of people living with AMD is expected to surpass 5.4 million by 2050, according to the NIH.

#### Treatments, cures, and costs

As of 2017, the global costs of treating AMD is estimated to exceed \$6.1 billion. While the age of the afflicted is predominantly over 65 years or older, the costs of treatment are not isolated to Medicare and Medicaid alone.

As older Americans remain in the workforce, the necessary treatment and their costs become more of a focus for employers.

- While there are various drugs to treat the symptoms of AMD, the primary drug prescribed to treat AMD is Lucentis.
- Lucentis, which received approval from the FDA in 2006, is reported to cost approximately \$2k per dose.

 A variety of new drugs are in the pipeline and expected to enter the market ranging from generics, alternative brands, and biosimilars. However price projections are unavailable.

As the U.S. population continues to age and live longer than prior generations, the amount of people living with AMD will continue to rise dramatically. AMD will continue to draw attention from pharmaceutical giants looking to expand their drug portfolio. However, this unfortunately entails the risk of an exceptionally expensive gene therapy or orphan drug to enter the market.

#### Sources:

Center for Disease Control, National Institutes of Health 1. "Learn About Age-Related Macular Degeneration" Center for Disease Control, accessed May 23, 2022, https://www.cdc.gov/ visionhealth/resources/features/macular-degeneration.html 2. "Age-Related Macular Degeneration" National Eye Institutes, accessed May 23, 2022, https://www.nei.nih.gov/learn-abouteye-health/eye-conditions-and-diseases/age-related-maculardegeneration

3. <sup>7</sup>Macular Degeneration Treatment Market: Technical Advancements and Promising Pipeline Products Assure Improved Growth" MedGadget, accessed May 23, 2022, https://www. medgadget.com/2021/08/macular-degeneration-treatmentmarket-technical-advancements-and-promising-pipelineproducts-assure-improved-growth.html



# **Clinical Spotlight (headline)**

## History of allergies increases risk of high blood pressure

### Adults with a history of allergies have an increased risk of coronary heart disease.

A new study used 2012 data from a crosssectional survey of the U.S. population. The allergic group included adults with at least 1 allergic disorder, including but not limited to asthma, respiratory allergies, digestive allergies, and skin allergies. The study included around 35,000 adults with an average age of 48.5 years and more than half of whom were women. The researchers found that individuals with a history of allergies between the ages of 18 and 57 had an increased risk of developing high blood pressure and coronary heart disease. "For patients with allergic disorders, routine evaluation of blood pressure and routine examination for coronary heart disease should be given by clinicians to ensure early treatments are given to those with hypertension or coronary heart disease," elaborated Yang Guo, PhD, and the study's lead author.1

Previous studies have reported an association between allergies and cardiovascular disease, but these findings had remained controversial. Longterm follow-ups alongside large cohort studies will be needed to confirm the findings. However, knowing that allergies may be an underlying cause of high blood pressure and heart disease may help management of these disease in individuals in the future.

## How do allergies contribute to high blood pressure?

There are a few theories on how allergies contribute to high blood pressure. When an allergen triggers an allergic response, histamines in the body boost blood flow into the area that the allergen attacks. This causes the immune system to send antibodies to that area, triggering



inflammation. Inflammation is the body's natural way of fighting off allergens and pathogens. Science shows that a long-lasting inflammatory response is an underlying factor in many chronic diseases including diabetes, high blood pressure, and heart disease.

Many allergy medications are antihistamines, which counter the body's inflammatory response. Antihistamines and pseudoephedrine (also found in many allergy medications), constrict blood flow by narrowing the blood vessels in the body. These narrow blood vessels can also lead to high blood pressure and increased heart rate. Another medication often prescribed for allergies or asthma is steroids. Steroids increase both blood pressure and blood sugar. Having high blood pressure and high blood sugar are important risk factors for coronary artery disease and stroke.<sup>2</sup>

In addition, nasal congestion associated with many allergy disorders may interfere with breathing while sleeping. Nasal congestion may promote or worsen sleep apnea. People with sleep apnea have an increased risk of high blood pressure. About 50% of sleep apnea patients have hypertension. Sleep apnea can also contribute to poor quality of sleep and shorter periods of sleep, which can raise someone's blood pressure.<sup>3</sup>

#### Sources:

1. Katie Glenn. "History of Allergies May Be Associated with Increased Risk of High Blood Pressure, Heart Disease", available at History of Allergies May Be Associated with Increased Risk of High Blood Pressure, Heart Disease - American College of Cardiology (acc.org)

2. Harvard Health Publishing. "Ask the doctor: Can allergies cause high blood pressure?", available at Ask the doctor: Can allergies cause high blood pressure? - Harvard Health 3. Alexa Fry. "How Sleep Apnea Affects Blood Pressure", available at How Sleep Apnea Affects Blood Pressure | Sleep Foundation

### **Pipeline** Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
spesolimab	Boehringer Ingelheim	Psoriasis (pustular flares)	6/1/2022
tebipenem pivoxil hydrobromide (HBr)	Spero	Complicated urinary tract infection (cUTI)	6/27/2022
tauroursodeoxy- cholic acid/sodium phenlbutyrate	Amylyx	ALS	6/29/2022
olipudase alfa	Sanofi	Acid sphingomyelinase deficiency	7/3/2022
tislelizumab	Novartis/Beigene	Esophageal squamous cell carcinoma	7/12/2022
vutrisiran subcutaneous (SC)	Alnylam	hATTR in adults	7/14/2022
cipaglucosidase alfa IV	Amicus Therapeutics	Late-onset Pompe disease	7/29/2022
Ranibizumab (biosimilar to Genentech's Lucentis)	Coherus	Wet AMD; Macular edema following RVO; mCNV	8/2/2022
teplizumab	Provention Bio	Type 1 diabetes	8/17/2022
betibeglogene autotemcel	Agios	pyruvate kinase deficiency	2/17/2022
deucravacitinib	Bristol-Myers Squibb	Psoriasis	9/10/2022
ublituximab	TG Therapeutics	MS (relapsing)	9/28/2022
futibatinib	Otsuka	Cholangiocarcinoma	9/30/2022
aflibercept (biosimilar to Regeneron's Eylea)	Viatris/Janssen	DME; Diabetic retinopathy; Macular edema following RVO; Wet AMD	10/31/2022

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Disability

**Brands losing patent** While these drugs are nearing the end of their patent term, the the release of generics may be delayed due to litigation or exclusivities.

Brand name	Generic name	Indication/use	Date generic available
Fragmin	dalteparin sodium	Venous thromboembolism (VTE)	May 2022
Alimta	pemetrexed disodium	Non-squamous non-small cell lung cancer	May 2022
Yosprala	aspirin; omeprazole	Secondary prevention of cardio- vascular and cerebrovascular events	May 2022
Mytesi	crofelemer	Diarrhea from HIV	June 2022
Eskata	hydrogen peroxide	Seborrheic keratosis	June 2022
Folotyn	pralatrexate	Peripheral T-cell lymphoma	June 2022
Ixempra Kit	Ixabepilone	Breast cancer	June 2022
Addyi	flibanserin	Premenopausal women with HSDD	June 2022
Keveyis	dichlorphenamide	Primary periodic paralysis	August 2022
Dulera	formoterol fum- arate; momet- asone furoate	Asthma	August 2022
Kinevac	sincalide	Gallbladder/pancreas disorders	August 2022
Oravig	mionazole	Antifungal	Sept. 2022
Yondelis	trabectedin	Liposarcoma/leiomyosarcoma	Oct. 2022

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