Responsiveness of Maximum Allowable Cost (MAC) To Generic Drug Inflation

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Abstract

Background

Generic prescription drugs are the most commonly utilized medications by Americans and the most frequently dispensed by pharmacies. Pharmacy Benefit Managers (PBMs) – who set reimbursement rates for pharmacies on behalf of health insurers and plan sponsors – principally employ maximum allowable cost (MAC) based reimbursement practices for generic medications, which lack transparency and predictability. In a time of significant global generic drug supply uncertainty, 3 Axis Advisors evaluated the responsiveness of historic MAC-based PBM reimbursement practices to significant generic drug price increases in order to quantify risks posed to supply chain economics should shortages or other disruptions occur that substantially alter generic drug prices.

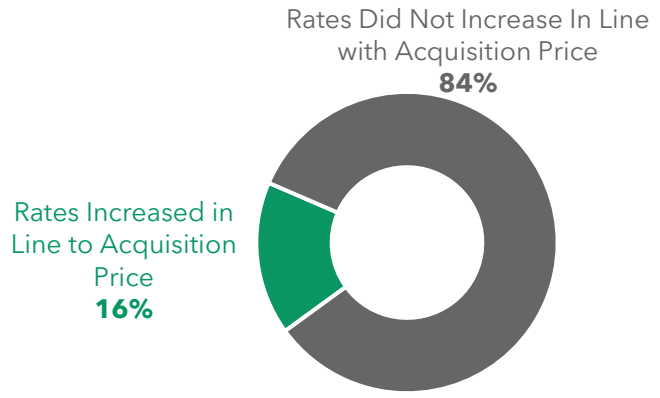
Methods

3 Axis Advisors obtained detailed prescription claims information from 1,392 pharmacies in 23 states on all claims dispensed between January 1, 2018 and March 26, 2020. An assessment was made to compare PBM reimbursement rates for drug ingredient costs based upon claims identified as paying under MAC-based rates to the underlying cost to acquire those same prescription drugs. Assessments were made across equally substitutable generic drug groups, year, and unique prescription drug plan.

Conclusions

For the top 50 health insurance plans, we identified 4,312 total occurrences in which the NADAC per unit experienced a 50% or more increase. For the same drugs, during the same time periods and reimbursed under the same Plans, we then identified 711 total occurrences in which the ingredient cost per unit experienced a 50% or more increase. As such, we found (as shown in **Figure 1**) that in only 16% of instances did prescription drug plans increase reimbursement for drugs that experienced extreme pricing increases (711 / 4,312).

FIGURE 1
PBM PAYMENT RATE INCREASES IN RELATION TO ACQUISITION COST INCREASES ON GENERIC DRUGS WITH EXTREME INCREASES IN ACQUSITION COST



Background

Generic drug cost deflation is a key driver that helps control overall inflation in U.S. drug costs.[1] Between 2016 and 2019, we estimate that, based on a stable Medicaid drug mix, generic drug pharmacy invoice acquisition costs have deflated by 61%, helping to partly offset the 42% increase in brand drug list prices.[2] [3]

However, generic deflation started to subside in the latter part of 2019 and has continued to wane in early 2020, dropping below 5% in February 2020.[4] This was down from 17% deflation just a year earlier.[5]

Against this backdrop, COVID-19 mitigation and suppression activities have swept the globe, introducing significant uncertainty into the global generic drug supply chain.[6] [7] Without reliable public information on exactly where active pharmaceutical ingredients (APIs) are produced, concerns are naturally arising on how China's and India's strategies to contain the spread of COVID-19 will impact supply of U.S. generic drugs imported from abroad.[8] [9] [10] [11] This initial concern has only been exacerbated in recent weeks by:

- Import and export restrictions by foreign governments[12] [13]
- Political leaders promoting protectionism[14]
- Temporary inventory stockouts due to the large-scale shift from 30-day to 90-day prescriptions, stressing normal wholesaler inventories[15] [16] [17]
- Rumors that a host of generic drugs could "potentially" be used to treat COVID-19, leading to speculative stockpiling of such drugs[18]

The confluence of these factors, combined with the broader inflationary tailwinds for generic drugs, could increase the likelihood of unpredictable and sharp generic inflation on an unknown number and quantity of generic drugs. Unfortunately, besides clear signs of shortages in inhalers and thinly-studied but heavily advertised COVID-19 "treatments" like hydroxychloroquine, it is currently too early to tell the difference between structural generic drug shortages (stemming from production disruptions) and temporary supply chain destocking (which will get replenished).[19] But it is irrefutable that our complex and interconnected global generic drug supply chain has been seriously disrupted, increasing the likelihood of escalating pricing volatility for the foreseeable future.

U.S. retail pharmacies are facing another uncertainty: whether reimbursement rates set by pharmacy benefit managers (PBMs) – often referred to as maximum allowable cost (i.e. MAC) rates – will keep pace with potential generic drug inflation.[20] [21] This is because MAC-based pricing is often based on aggregating data, and not directly linked to acquisition costs. Consequently, pharmacies can earn more profit on some drugs, and may lose money on others.[22]

Unlike other efficient commodity markets (e.g. gasoline), pharmacy payment rates are set by PBMs.[23] Because different generic manufacturers may charge different amounts for equally interchangeable generic drugs, a PBM MAC list is intended to incentivize the purchase of the least costly generic drugs available in the market, regardless of available pricing benchmarks. According to the American Academy of Managed Care Pharmacy (AMCP), "MAC price reimbursement is a more accurate pricing tool than other payment alternatives for generic drug reimbursement because MAC prices are updated frequently to keep pace with market changes in the purchase prices of generic drugs available to pharmacies."[24] In so far as MAC lists represent the PBM industry's preferred method for pricing generic drugs, the lack of transparency around MAC-based pricing means such payment rates can vary widely from one plan to the next, creating incentives for the pharmacy to serve certain patients over others based upon their drug plan.

Given the risks for rapid generic drug inflation due to COVID-19, in this study we set out to design methodology to help answer the following question: If generic drugs inflate in the coming months, will PBMs responsively adjust their private and largely unregulated MAC pricing lists to ensure that retail pharmacies will generate enough sustainable revenue to continue to dispense medications to their patients?

It would be unfortunate if disconnected MAC prices compromised patient access and slowed, or even disincentivized, the dispensation of certain medications, such as prospective COVID-19 treatments. Clearly, if any generic becomes a proven treatment, it will experience an unprecedented surge in demand, and a resulting surge in price until more supply is brought to market. If MAC rates set by PBMs do not keep track with

these market-driven cost movements, retail pharmacies could be forced to either dispense the drug at a steep loss or choose not to assume the financial risk of stocking the medication. This is an unnecessary and avoidable economic problem that could inhibit necessary widespread access to potentially lifesaving COVID-19 treatments for patients across this country.

It is our hope that a better understanding of how MAC rates have historically tracked in relation to acquisition costs for drugs that experienced large price increases will help inform and quantify the nature of the problem that could arise in the coming months.

Research Objective

The disconnect between PBM-set MAC reimbursement rates and pharmacy acquisition costs for generic drugs introduces economic uncertainty into how the U.S. drug supply chain will respond to the COVID-19 driven shock. MAC rates must keep track with drug price inflation to ensure that pharmacies remain viable and have proper incentive to dispense impacted medications to patients.

The purpose of this research brief is to determine to what extent PBM MAC prices, which form the basis of drug ingredient costs paid to their network pharmacies for generic drugs, have been responsive to large price increases on generic drugs.

Methodology

Database creation

3 Axis Advisors obtained detailed prescription claims information from 1,392 pharmacies in 23 states on all claims dispensed between January 1, 2018 and March 26, 2020.[25] This database includes claims for all payers at that pharmacy, including patients that lacked prescription drug coverage and paid cash. Notably, each claim included the following information:

- Date of service
- Ingredient cost paid
- Quantity dispensed
- Plan information [i.e. Bank Identification Number (BIN), Processor Control Number (PCN), and Group ID]
- National Drug Code (NDC)
- Basis of reimbursement

We removed any claims within the data that were reversed, voided, cancelled, or had multiple payers. We then filtered the claims to those paid with a Basis of Reimbursement (NCPDP Field# 522-FM) equal to 6 or Ø6.[i] [26] We then aggregated all data by Month and Year of service, NDC, and Plan.[ii]

The next step of our work was to bring in the CMS National Average Drug Acquisition Cost (NADAC).[27] NADAC is the most extensive database of pharmacy acquisition costs (i.e. invoice costs) available to the public. We first aggregated NADAC for every national drug code (NDC) by Month and Year. We then joined the NADAC database to our aggregated claims database on an inner join based upon NDC, Month, and Year. This resulted in an intermediate database that contained the total ingredient cost and quantity dispensed in each month and year for all NDCs in the database, along with the NADAC per unit for that NDC at the same time.

We then joined this intermediate database on NDC with clinical drug information obtained from Wolters Kluwer's MediSpan PriceRx database.[28] To classify drugs into substitutable groups, we used Medi-Span's Generic Product Packaging Code (GPPC).[iii] We aggregated ingredient cost, dispensed units, and total claims by the GPPC. We then filtered the database to just generic claims on the basis of Medi-Span's Brand Name Code (BNC) and FDA License Type. Generics were defined based upon a BNC equal to "G" and FDA license type equal to Abbreviated New Drug Application (ANDA).

Lastly, to eliminate the risk of units of measure mismatches between pharmacy claims data and NADAC, we filtered the final database to oral solids,

[i] According to the National Council for Prescription Drug Programs (NCPDP) Basis of Reimbursement value Ø6 "indicates when the ingredient cost

[ii] A unique prescription drug plan was identified based upon the combination of BIN, PCN, and Group ID

[iii] Drugs with equivalent first five digits of their GPPC are defined generic equivalents that are substitutable

which were defined based upon Medi-Span's dosage form description including only tablet and capsule formulations.

Our final database captured 28,703,960 generic claims dispensed by 1,392 pharmacies between January 1, 2018 and March 26, 2020. The database includes a total of 1,627 different substitutable generic drug groups on the basis of Medi-Span's Generic Product Identifier (GPI).

Analysis

Our first analytical task was to identify all generic drugs that experienced a significant increase in NADAC per unit during the study period. We defined a significant price increase to be an increase of 50% or more over any six-month period and an absolute price increase value that was greater than $0.05 per unit.[iv] Out of the 1,627 substitutable generic drug groups, we identified 101 that experienced at least one significant monthly price increase during the study period.

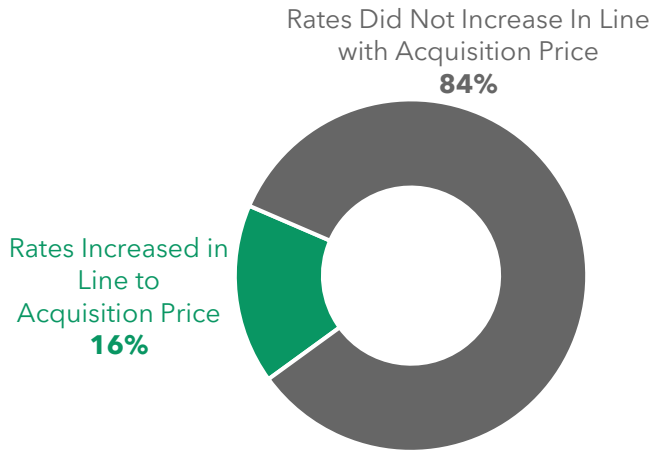
Our next task was to replicate this analysis using the ingredient costs per unit reported by the top 50 Plans (by claim count) on the same 101 drugs. We counted the number of months in which the Plan increased its paid ingredient cost per unit by 50% or more (the numerator) when the drug's NADAC per unit increased by 50% or more (the denominator). Note that if the Plan did not have any claims dispensed in a month for a drug that experienced a significant price increase, we dropped this data point from the denominator. We also only counted ingredient cost increases when the absolute ingredient cost per unit was greater than the absolute NADAC per unit. In other words, we did not give a Plan credit for payment increases if the resulting reimbursement was still insufficient to cover the drug's acquisition cost which can occur with PBM MAC rates as advocated for by AMCP.[29]

Ultimately, we arrived at a ratio that measured how often the top 50 Plans instituted a significant ingredient cost increase in months characterized by significant NADAC increases.

Results

For the top 50 Plans, we identified 4,312 total occurrences in which the NADAC per unit experienced a 50% or more increase. For the same drugs, during the same time periods and reimbursed under the same Plans, we then identified 711 total occurrences in which the ingredient cost per unit experienced a 50% or more increase. As such, we found (as shown in **Figure 2**) that in only 16% of instances did prescription drug plans and their PBMs increase reimbursement for drugs that experienced extreme pricing movements of more than 50% and absolute per unit changes of more than $0.05 (711 / 4,312).[v]

FIGURE 2
PBM PAYMENT RATE INCREASES IN RELATION TO ACQUISITION COST INCREASES ON GENERIC DRUGS WITH EXTREME INCREASES IN ACQUSITION COST



Discussion

The revenue generated by retailers in properly functioning commodity markets, such as gas stations, fluctuate in line with input prices. In other words, when a retail gas station's gasoline acquisition cost increases,

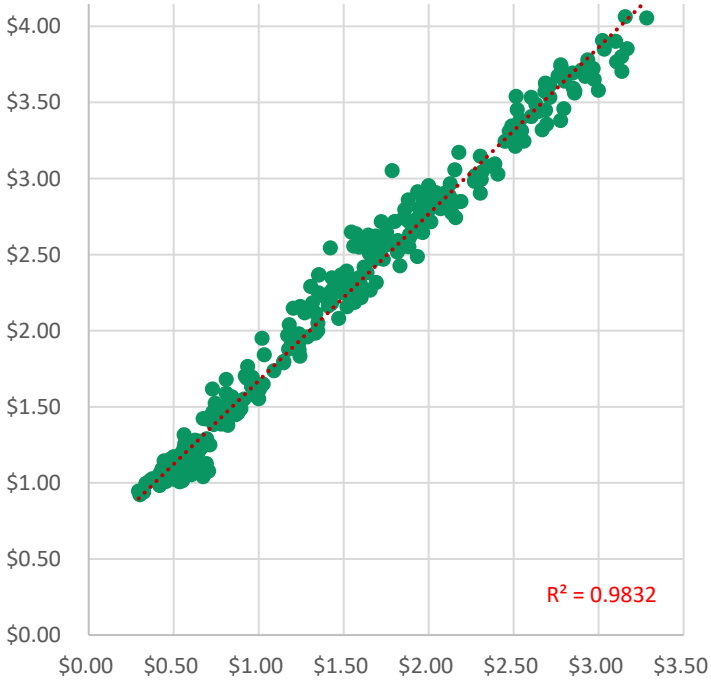
[iv] This was to remove drugs that flipped back and forth between $0.01 to $0.02 or $0.02 and $0.03, like acetaminophen

[v] To aid in understanding the relationship between PBM MAC-based generic reimbursement and acquisition costs, Appendix A presents detailed data on the top 15 drugs that experienced significant price increases by the top 5 prescription drug plans

so does its sales price, and vice versa. Ample competition, combined with lack of product differentiation, forces all retailers to price in a "cost-plus" manner that produces a modest, but sustainable return on investment. This creates a very strong correlation between the product input and output costs of a retail gas station. **Figure 3** presents a scatter plot of the monthly "spot price" of gasoline, as priced on the Gulf Coast (x-axis), versus average retail gasoline prices for all gasoline formulations (y-axis).[30] The former is a proxy for a gas station's input cost while the latter is a proxy for its output cost.

As shown in **Figure 3**, the correlation between these two measures is very strong, with a R-squared of over 0.98. On inspection of **Figure 3**, it becomes clear that input costs are a very good predictor of output revenue for gasoline. By simply knowing the spot price of gasoline in any given month, one can predict (using a linear regression) the retail output cost in any for the same month with a relative standard error (RSE) of just 6%. As such, gasoline retail input prices are a good predictor of retail output prices, an unsurprising conclusion in an efficient, cost-plus commodity market.

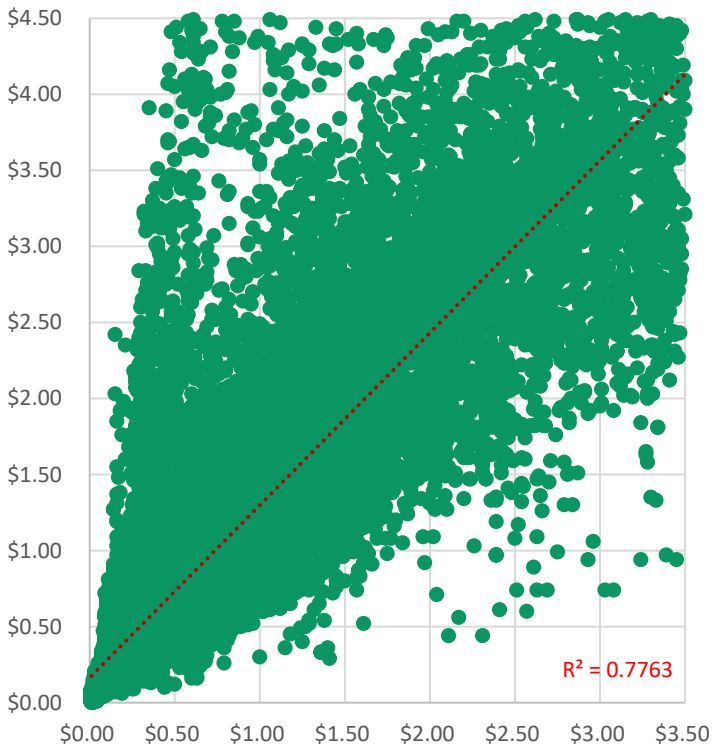
FIGURE 3
US REGULAR ALL FORMULATIONS RETAIL GASOLINE PRICES VS. US GULF COAST CONVENTIONAL GASOLINE REGULAR SPOT PRICE FOB



Contrast this with generic oral solid drugs. **Figure 4** plots monthly retail pharmacy input costs (i.e. acquisition cost per unit[vi]) versus output revenue (i.e. revenue per for unit) for 1,627 generic drugs dispensed by a group of 1,392 retail pharmacies from our study. Each dot plots the input cost and output cost for one drug in one month. We focused on generic drugs with an output revenue and input cost of $4.50 per unit and less and $3.50 per unit or less, respectively, to place **Figures 3 & 4** on the same scale.

Based on **Figure 4**, it should be clear that input costs are not going to predict output revenue for retail pharmacies nearly as well as they do for retail gas stations. The math proves this out. When we use acquisition cost for each drug to predict revenue per unit in any given month (from **Figure 4**), we calculate a RSE of 52%, suggesting generic drug acquisition costs to be a very poor predictor of generic drug pharmacy revenue.

FIGURE 4
GENERIC DRUG REVENUE PER UNIT VS. ACQUISITION COST PER UNIT



[vi] As represented based upon National Average Drug Acquisition Cost (NADAC)

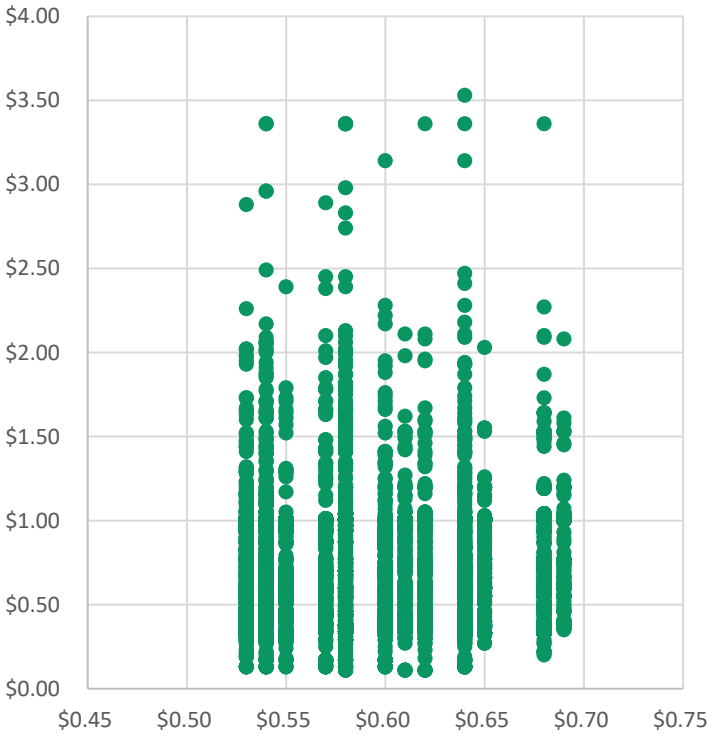
As such, generic drugs, despite being a commodity product lacking substantive differentiation, are not priced in an efficient cost-plus model. Instead, PBMs set the ingredient cost and dispensing fee that retail pharmacies will receive for each generic drug at any given time, and that payment rate is not a cost-plus model.

On a typical generic prescription drug claim, ingredient cost is one of two components of reimbursement: the other being dispensing fee. We have shown in this study the variability and unpredictable nature of ingredient-based reimbursement to pharmacies. In contrast, dispensing fees are fixed amounts that pharmacies receive per prescription. However, the dispensing fee is a relatively insignificant portion of reimbursement for pharmacies. Our analysis of the population of claims data in our study arrives at an average dispensing fee of just $0.70 per prescription (note this is not per unit). If this were the only source of revenue for pharmacies, this would mean they would generate a profit of just $0.70 on each claim filled for patients, a fraction of the ~$10 per claim required to cover operating costs. [31] Consequently, these miniscule dispensing fees leaves ingredient cost (i.e. MAC rates) as the primary source of pharmacy revenue.

To get a sense for how MAC rates can vary across plans, we must drill deeper into one drug. To illustrate, we have chosen a decades-old antibiotic – azithromycin (generic Zithromax) – which recently regained notoriety as an investigational COVID-19 treatment when taken in together with anti-malarial drug hydroxychloroquine (generic Plaquenil).[32] **Figure 5** presents a scatter plot of the retail pharmacy output revenue (i.e. PBM reimbursement per unit) and input costs (i.e. acquisition cost per unit) of azithromycin 250 mg tablets by month-year and plan. As with earlier charts, this chart is based on claims data between January 1, 2018 and March 26, 2020 for claims reimbursed based upon a PBM MAC rate.

The encouraging takeaway from **Figure 5** is that azithromycin has "traded" (or been acquired) in a relatively narrow range over the past 27 months – with a range of $0.53 to $0.69 per unit. Unfortunately, ingredient costs paid by PBMs to pharmacies did not exhibit this same level of stability, ranging from $0.11 to $3.53 per unit. We can clearly see from the chart that even when the true acquisition cost is perfectly stable (a vertical line), rates paid to pharmacies can vary significantly depending on drug plan and PBM. Consider the left most vertical line in **Figure 5**, which shows all ingredient costs paid to pharmacies for dispensation of azithromycin 250 mg tablets in a month when its NADAC was exactly $0.53 per unit. When acquisition costs were fixed, PBM reimbursement ranged from $0.13 (75% under cost) to $2.88 per unit (443% above cost) despite an unchanging acquisition cost.

FIGURE 5
AZITHROMYCIN 250 MG COMPARISON OF PBM PAID PER UNIT TO ACQUISITION COST PER UNIT

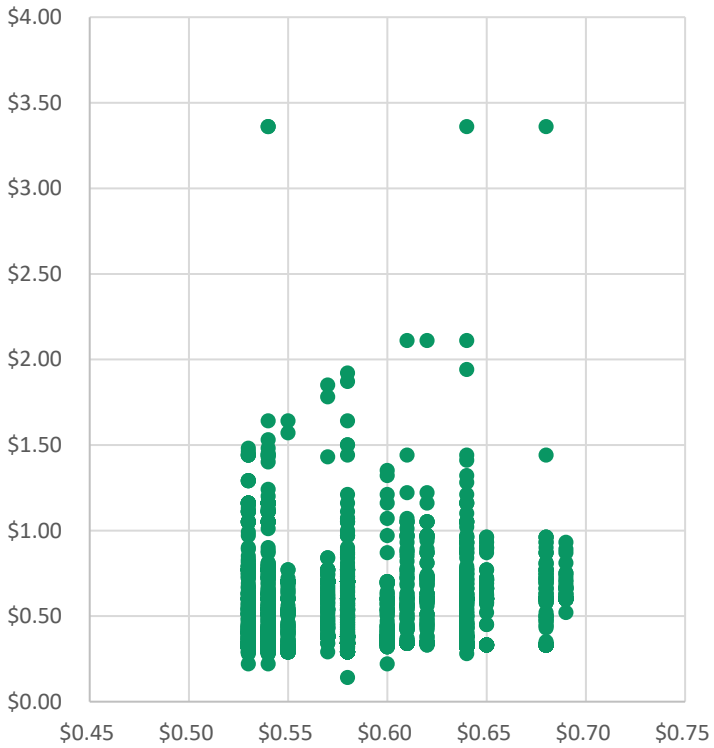


Framing this in the context of gasoline, this pricing behavior in generic drugs - where retail pharmacies receive different revenue depending on the patient's prescription drug plan - would be akin to a retail gas station receiving a vastly different price per gallon depending on the credit card used by the consumer. Hypothetically, if the consumer chose to use her Capital One Venture Card, the gas station would get paid $3.00 per gallon, whereas if she chose to use her American Express Gold Card the gas station would get paid $0.50.

But even this understates the variability in ingredient costs reimbursements pharmacies are receiving. This is because different plans administered by the same PBM can pay out vastly different ingredient costs. As can be

seen in **Figure 6** (on the next page), when we filter **Figure 5** to all claims processed by **only one** of the top three PBMs in the United States we still see a significant amount of variability.[vii] Again, all rates shown in **Figure 6** have been set by the exact same company (i.e. PBM). The differences in payments by the PBM for this same drug are attributed to the different prescription drug plans that PBM is administering. At a time when the drug

FIGURE 6
AZITHROMYCIN 250 MG COMPARISON OF PBM PAID PER UNIT TO ACQUISITION COST PER UNIT (FIXED TO SINGLE PBM)



cost was $0.53 per unit (left most column), this PBM paid pharmacies anywhere between $0.29 per unit (45% below costs) and $1.48 per unit (179% above costs).

So, we must extend our gas station metaphor to consider that even different cards offered by the same company can pay a retailer differently. PBM MAC-based generic drug reimbursement practices are equivalent to an American Express Gold Card paying a retailer $0.50 per gallon, while an American Express Blue Cash card could pay a retailer $1.50 per gallon.

[vii] Single PBM was identified based upon RX Bank Identification Numbers (BIN)

About 3 Axis Advisors LLC

3 Axis Advisors LLC is an elite, highly specialized consultancy that partners with private and government sector organizations to solve complex, systemic problems and propel industry reform through data-driven advocacy. With a primary focus on identifying and analyzing U.S. drug supply chain inefficiencies and cost drivers, 3 Axis Advisors LLC offers unparalleled expertise in project design, data aggregation and analysis, government affairs and media relations. 3 Axis Advisors LLC arms clients with independent data analysis needed to spur change and innovation within their respective industries. Co-founders Eric Pachman and Antonio Ciaccia were instrumental in exposing the drug pricing distortions and supply chain inefficiencies embedded in Ohio's Medicaid managed care program. They are also the co-founders of 46brooklyn Research, a non-profit organization dedicated to improving the transparency and accessibility of drug pricing data for the American public. To learn more about 3 Axis Advisors LLC, visit www.3axisadvisors.com.

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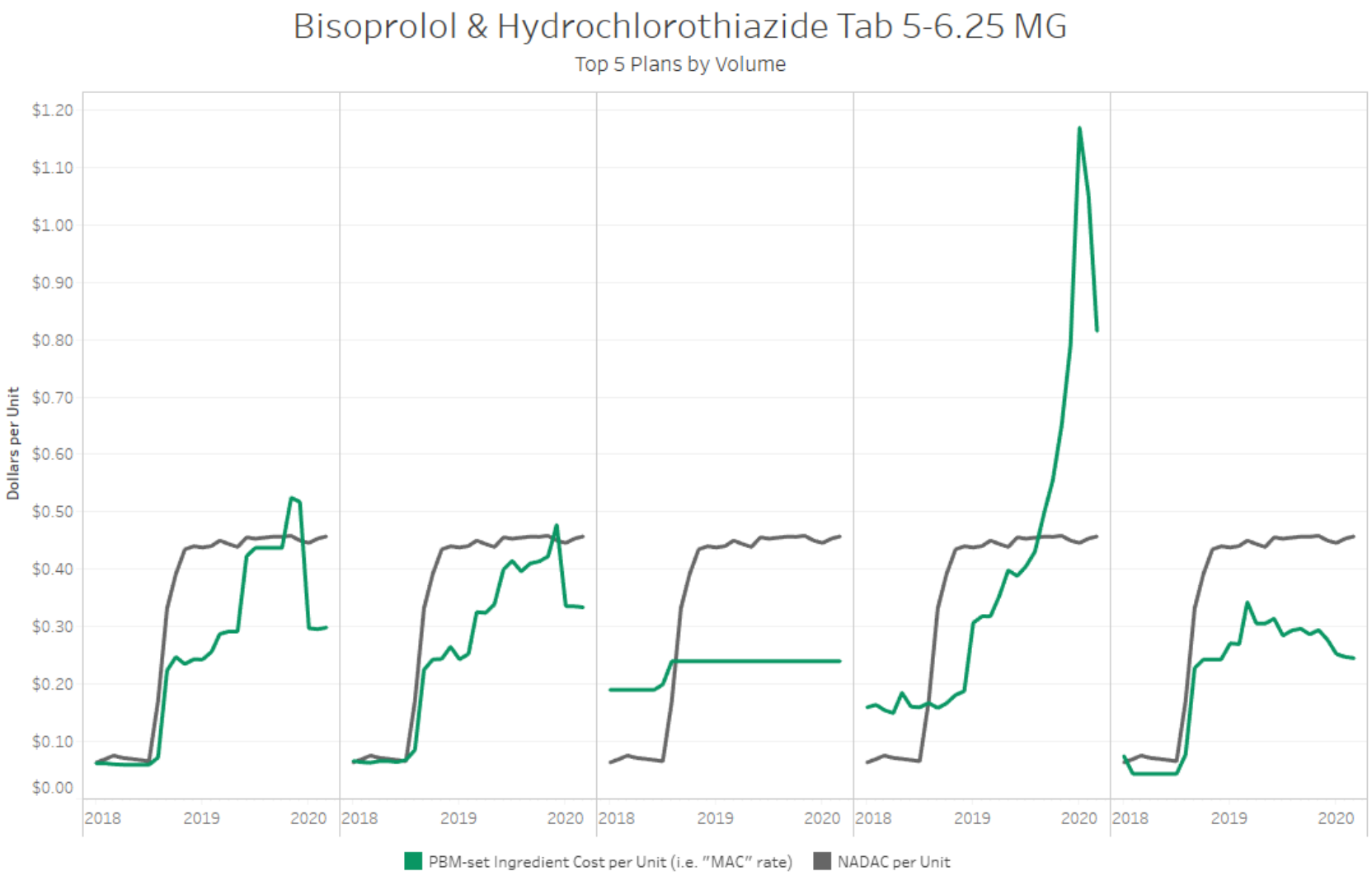
Appendix A



All PBM Ingredient Costs in this figure are limited to claims dispensed under a Basis of Reimbursement (NCPDP Field# 522-FM) equal to MAC (i.e. 6 or Ø6)

Bisoprolol Fumarate Tab 5 MG

Top 5 Plans by Volume

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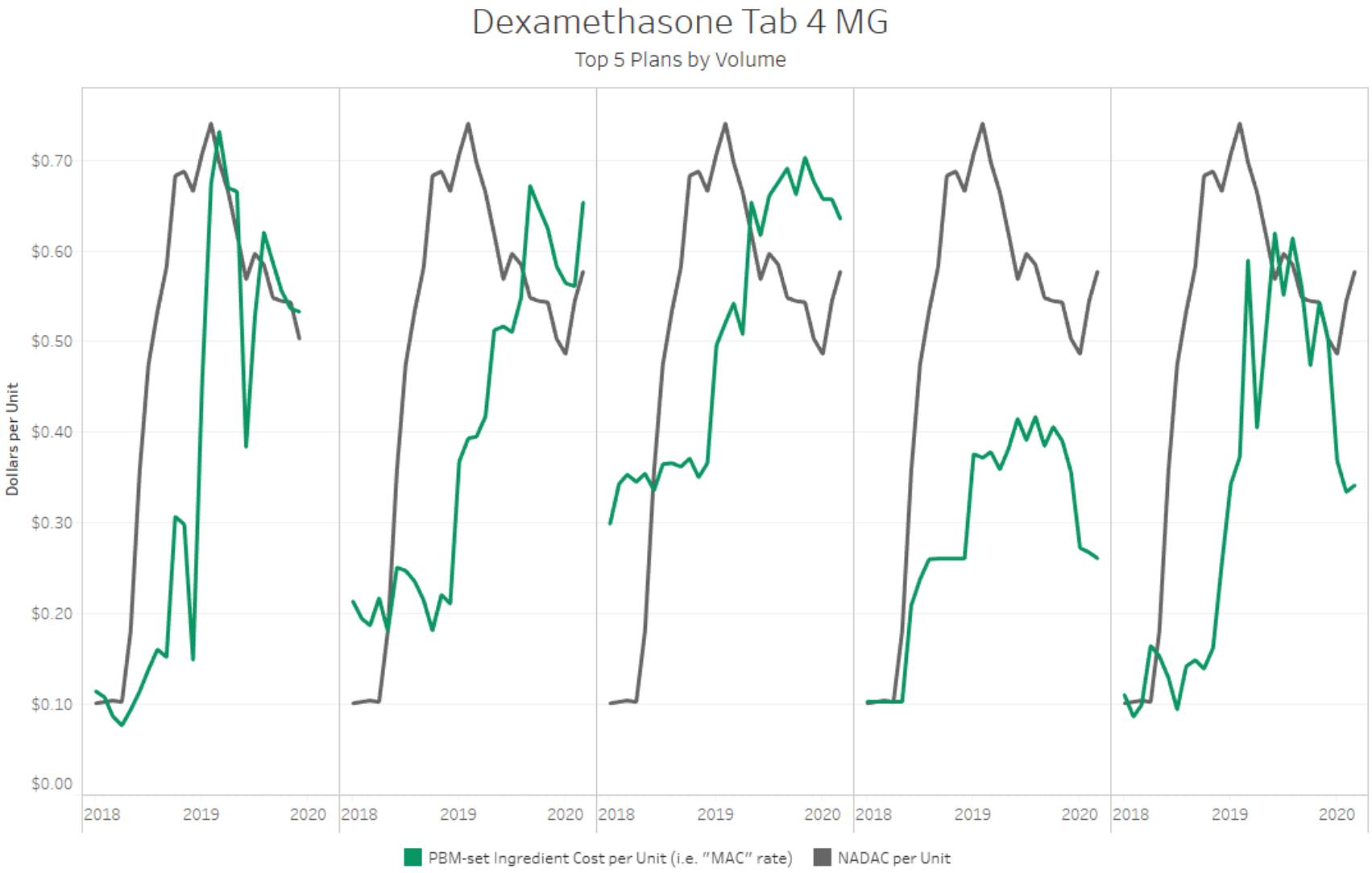

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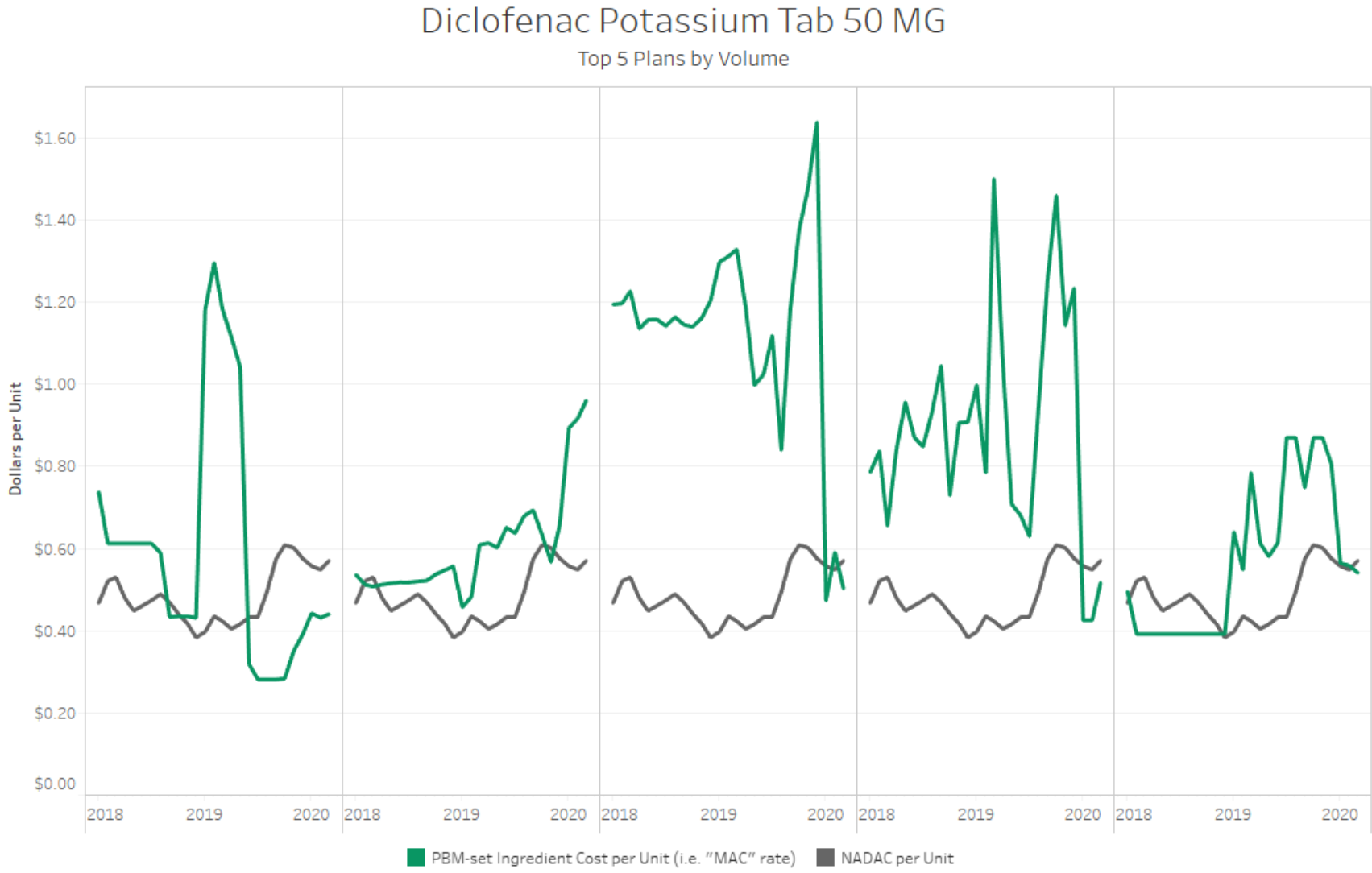

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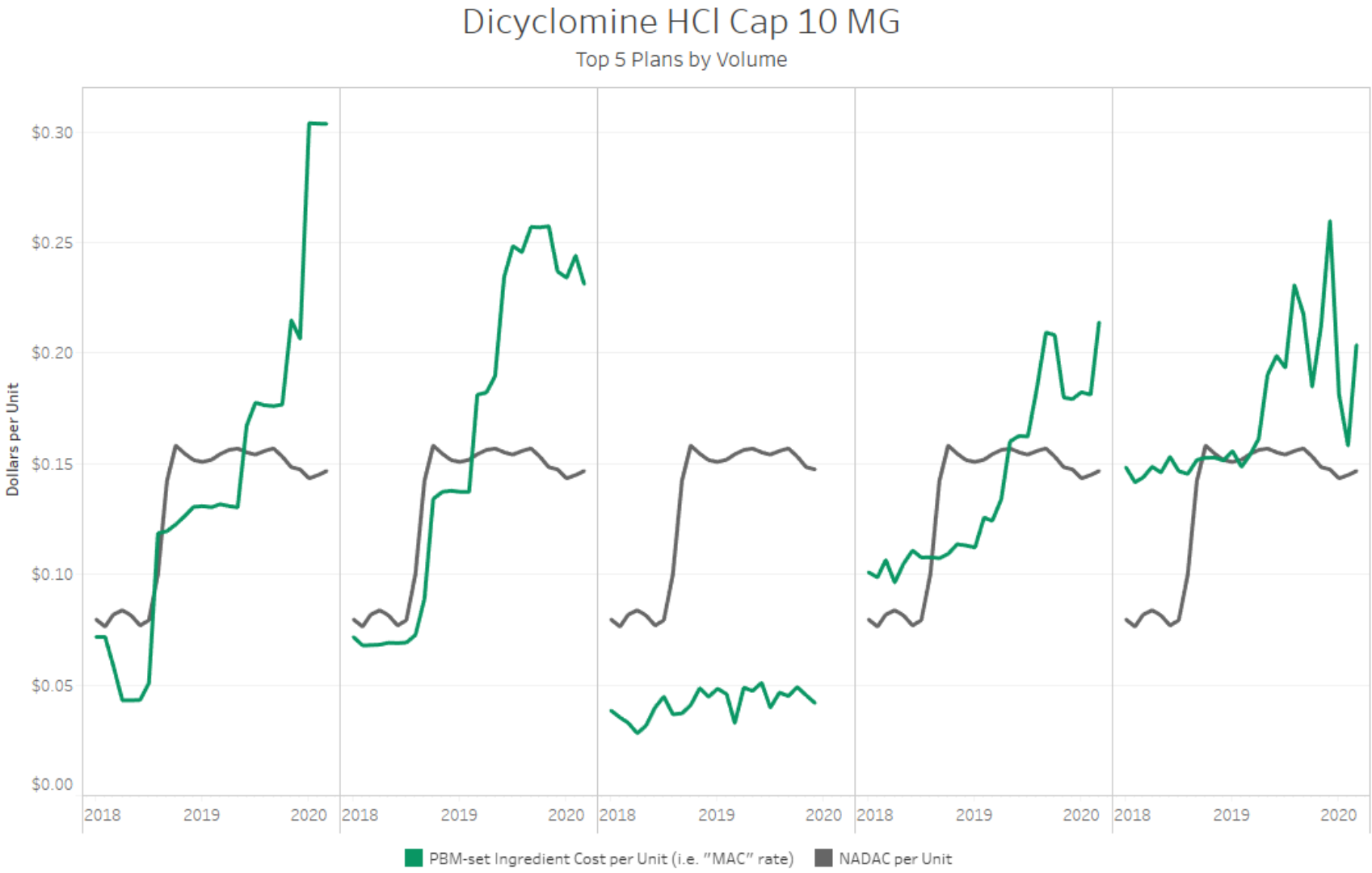

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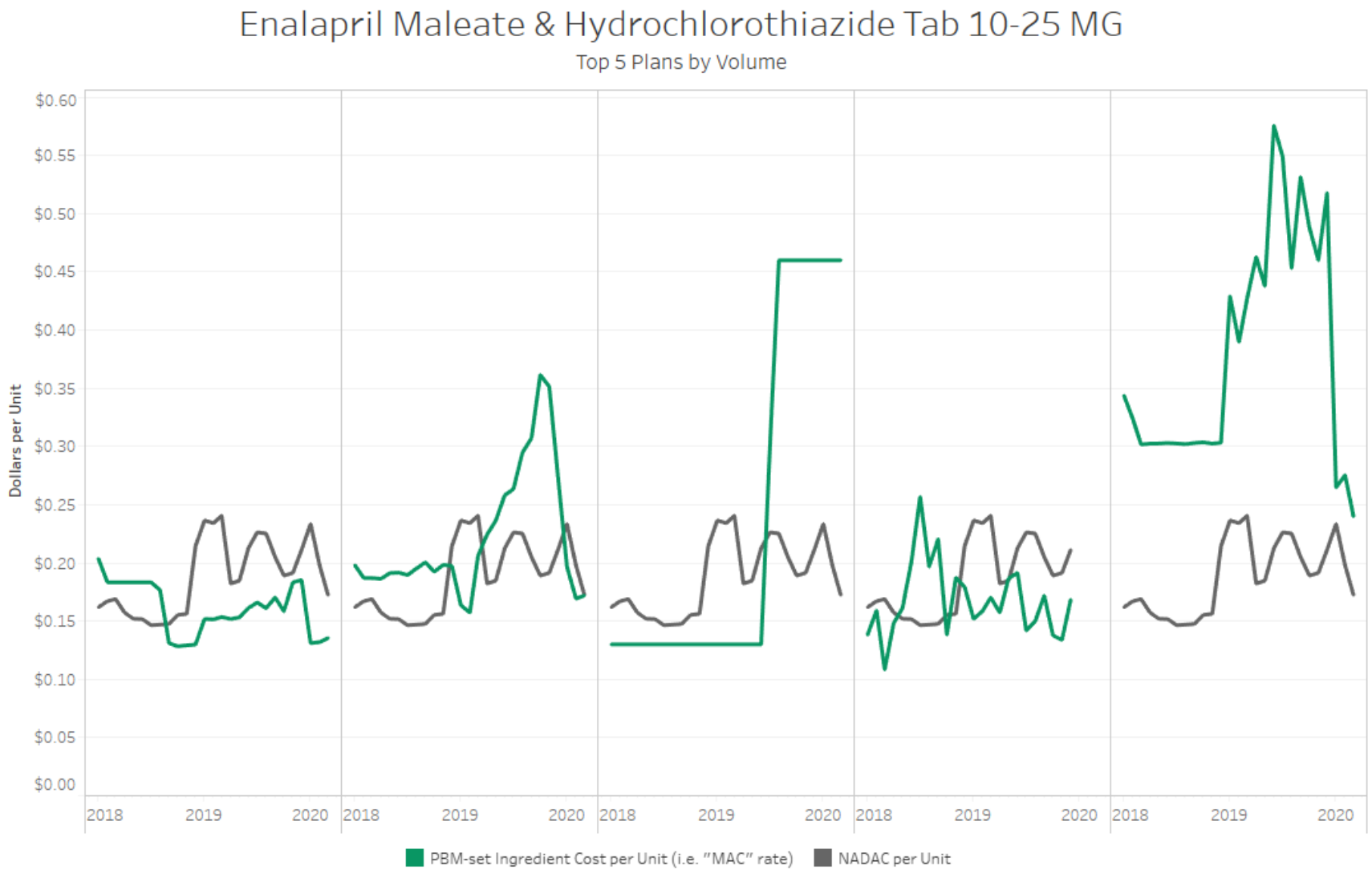

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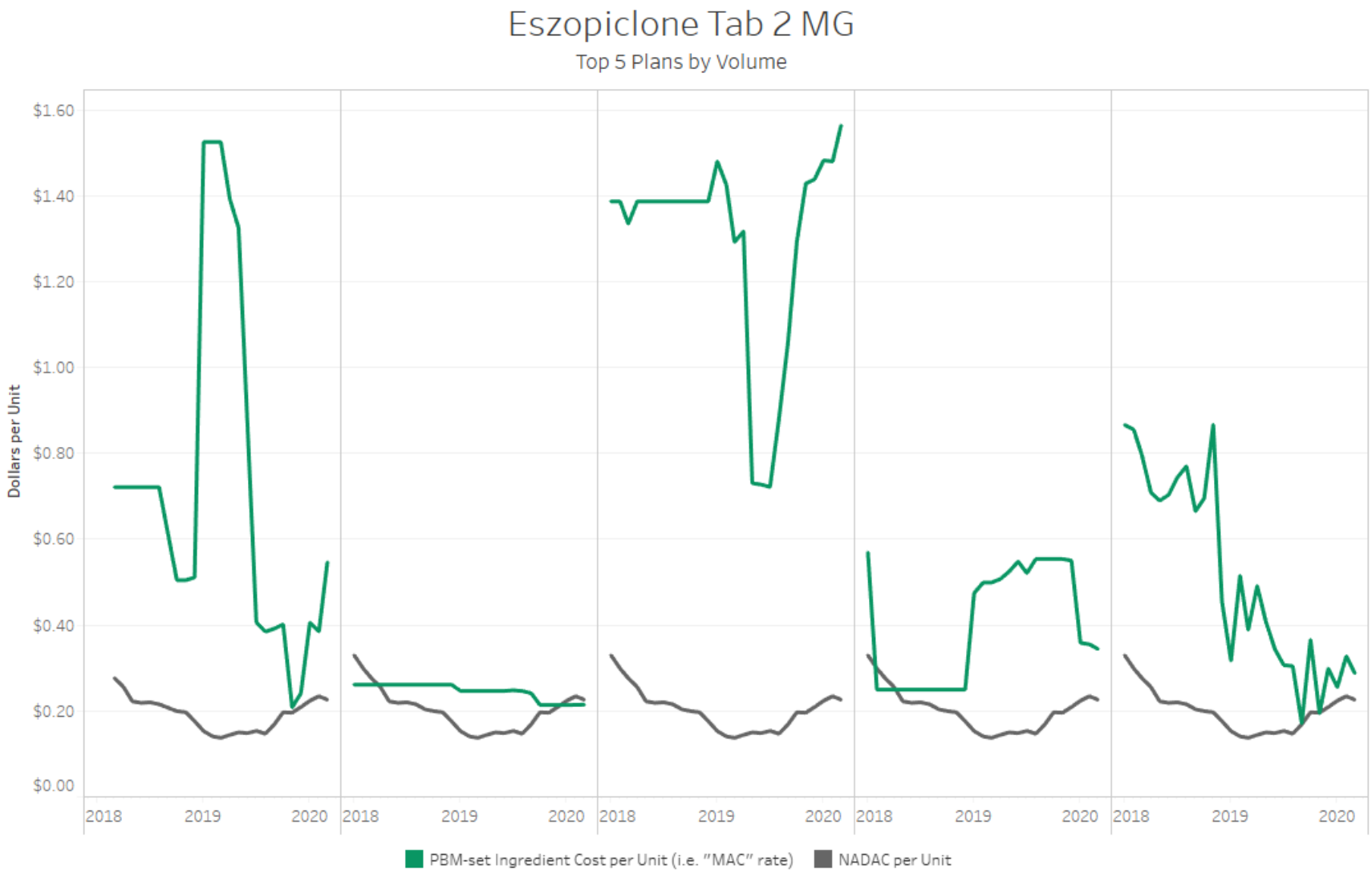

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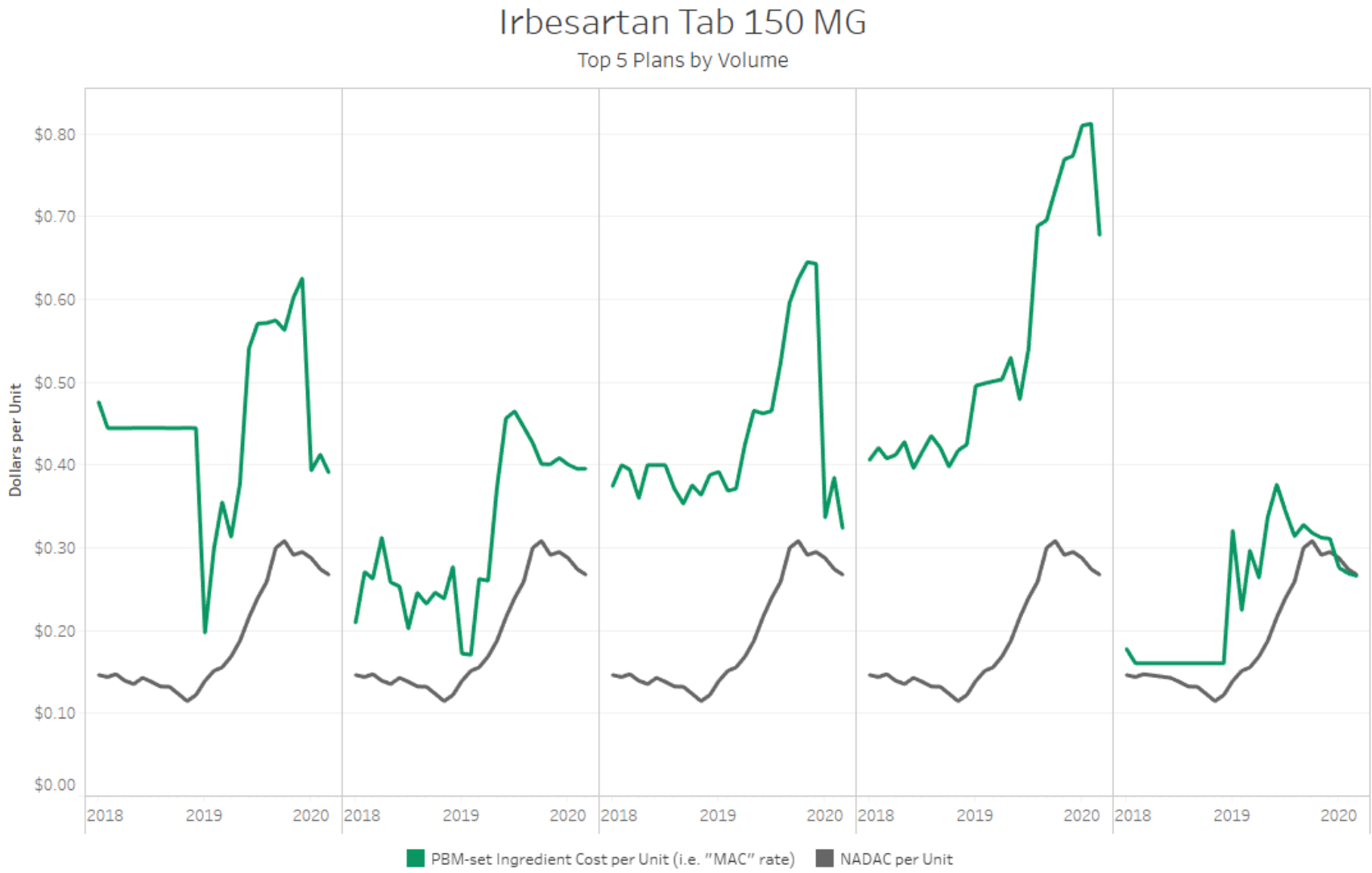

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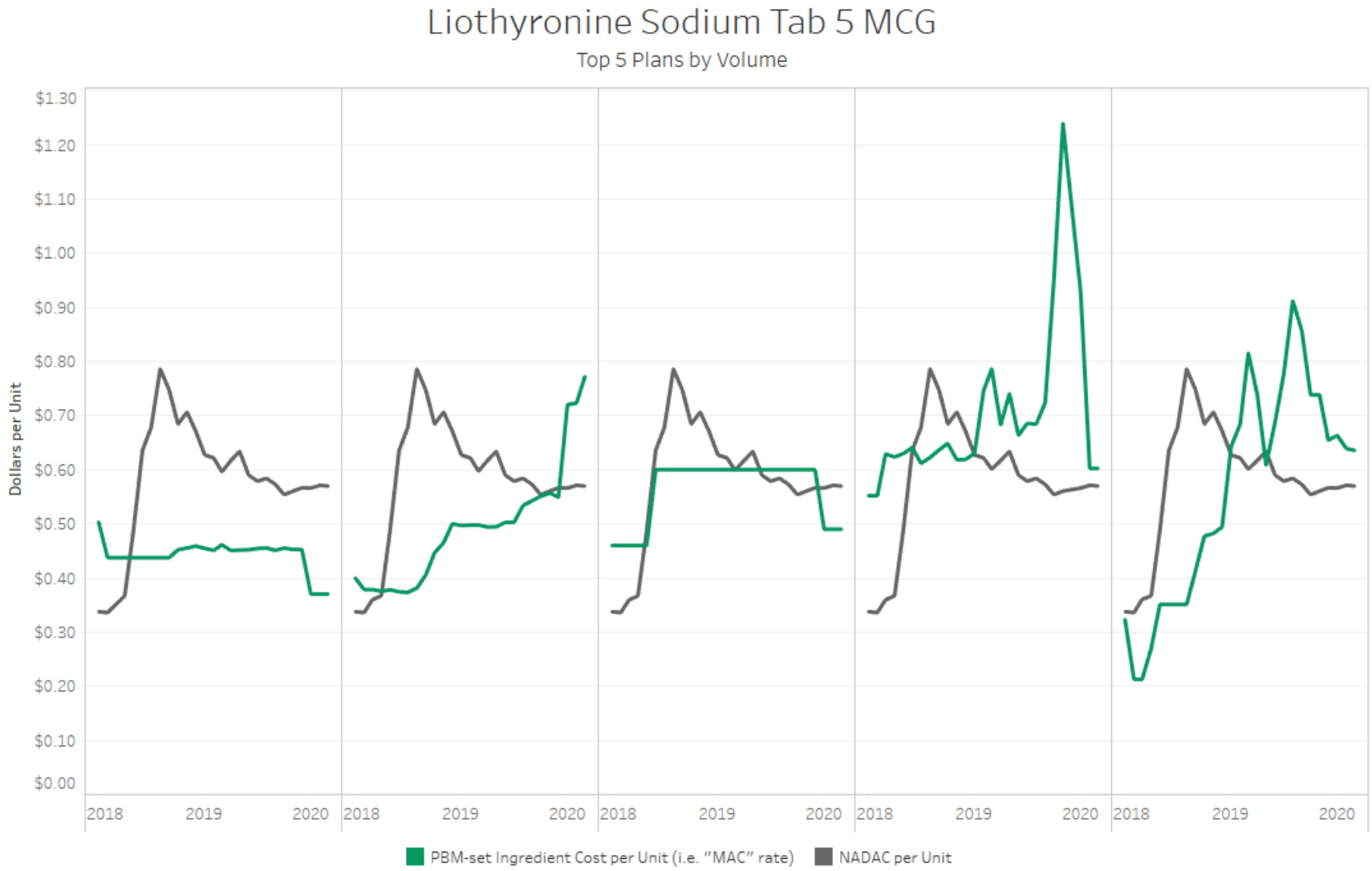

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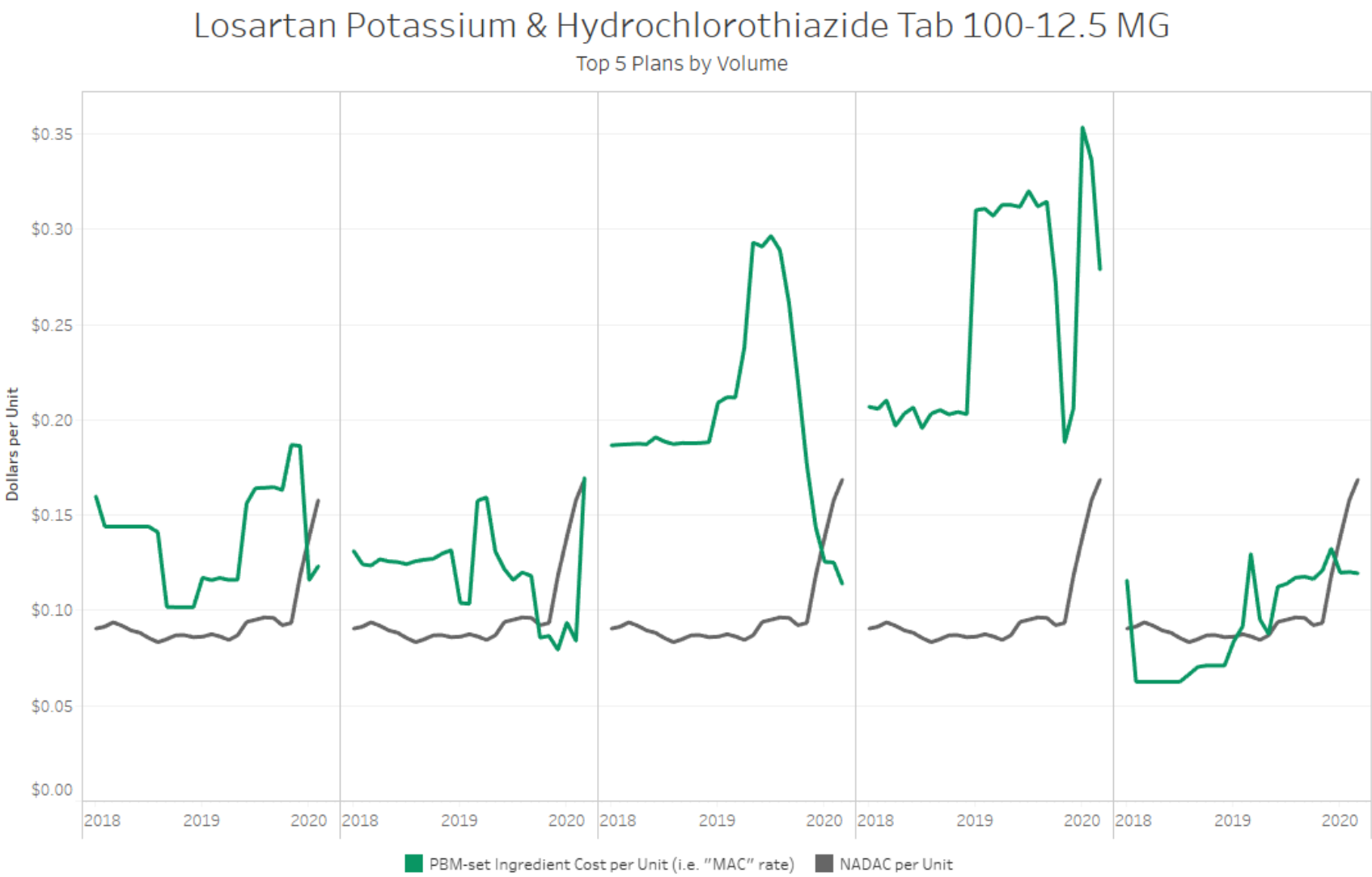

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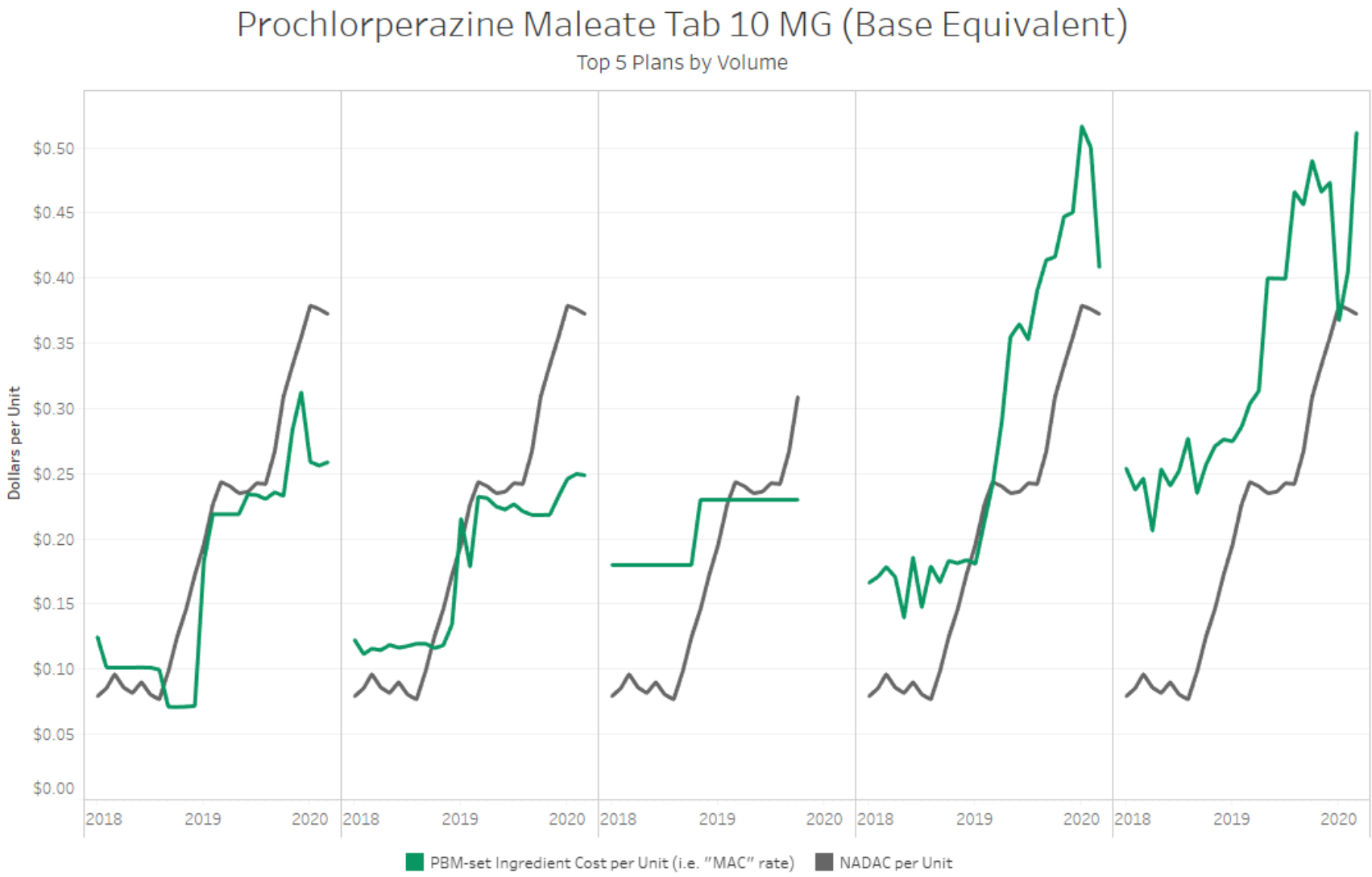

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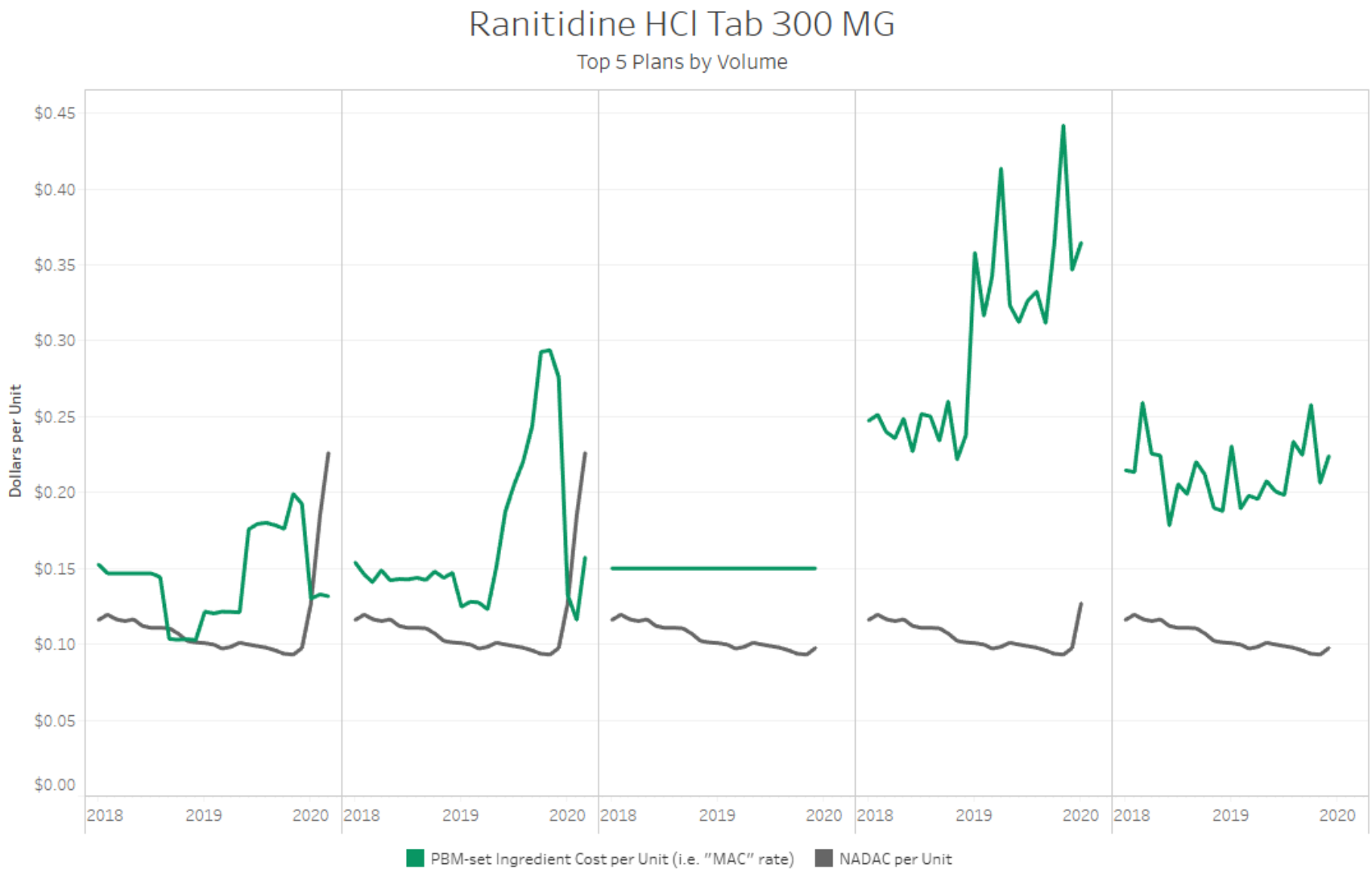

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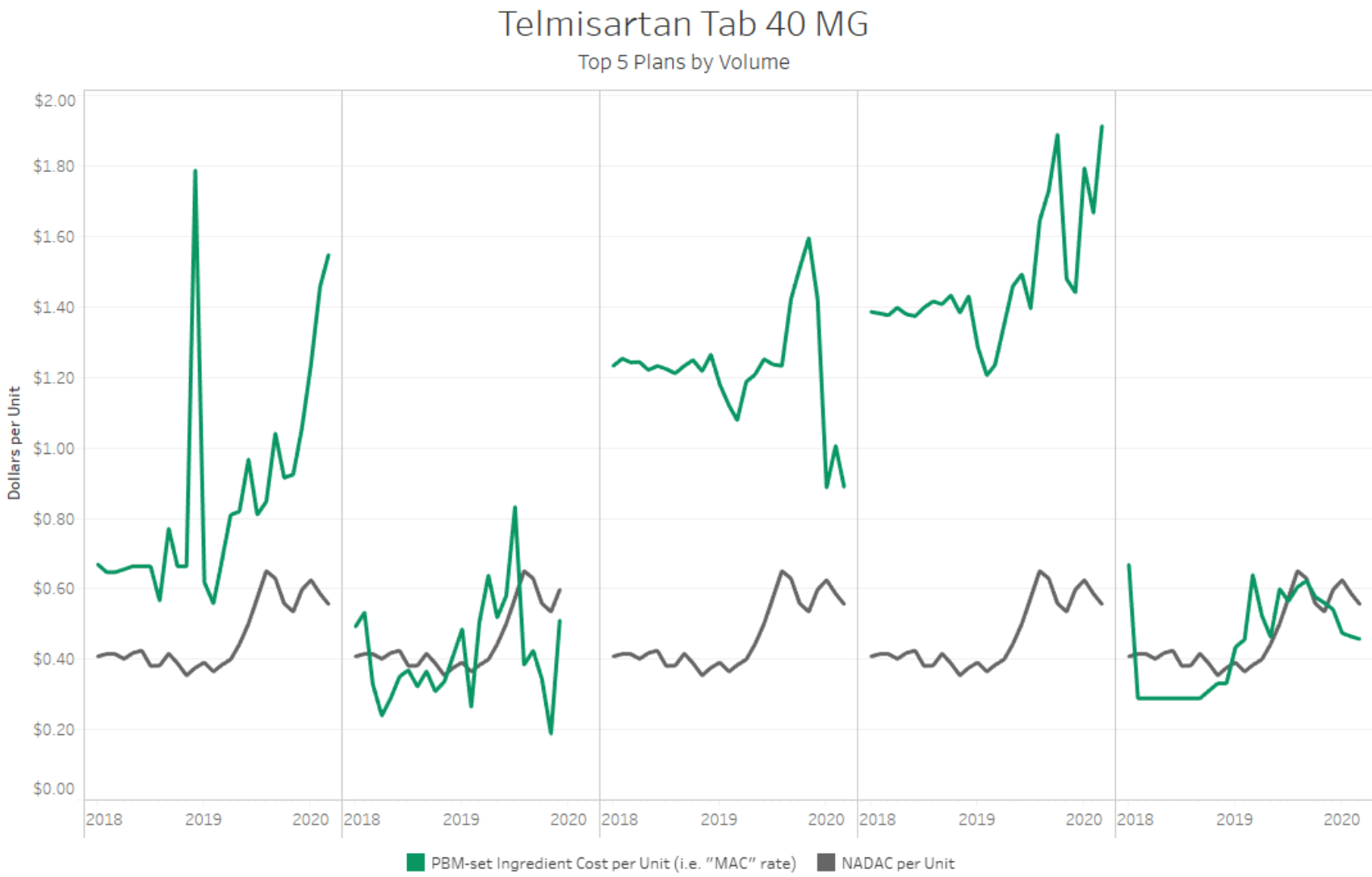

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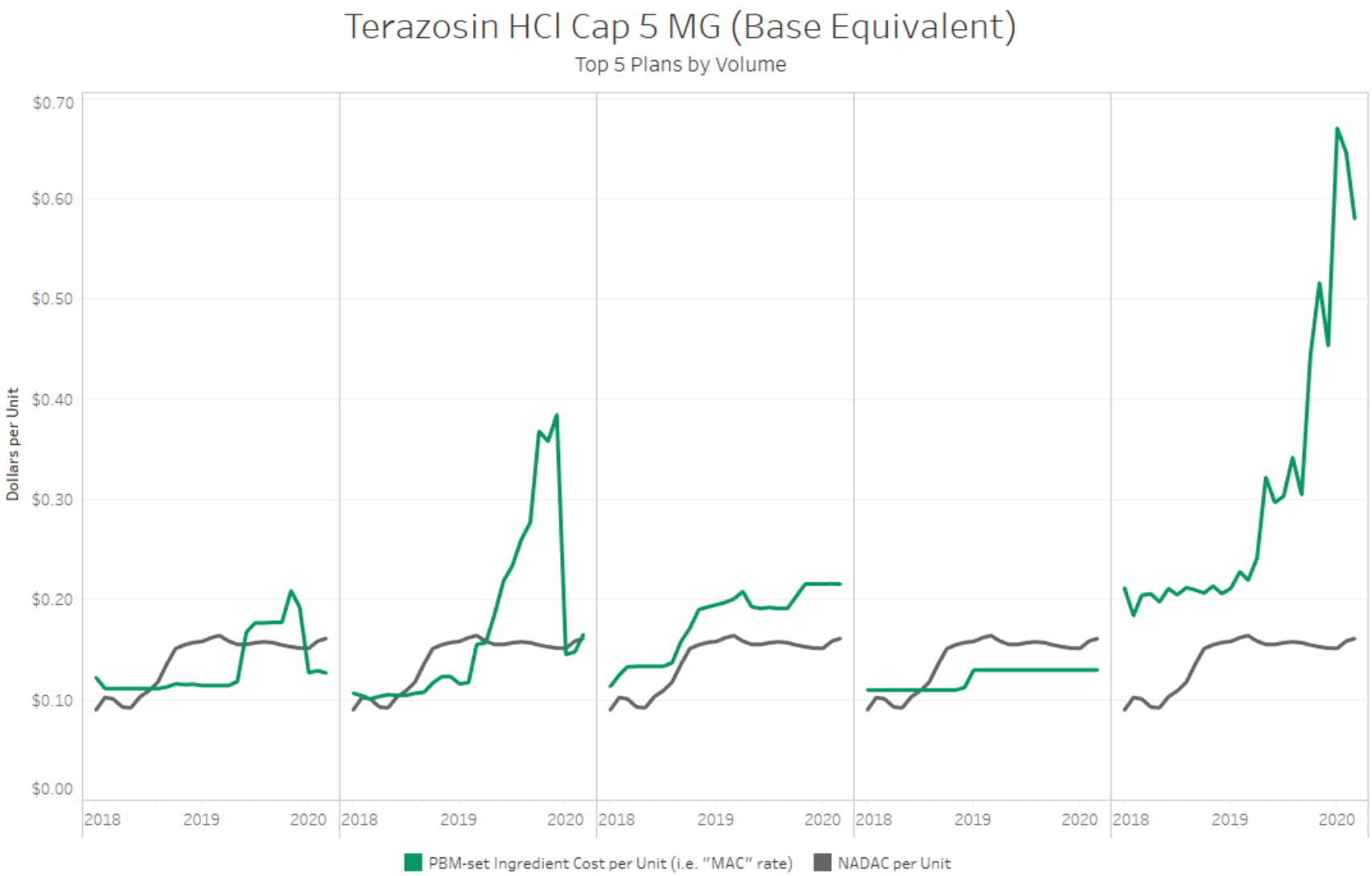
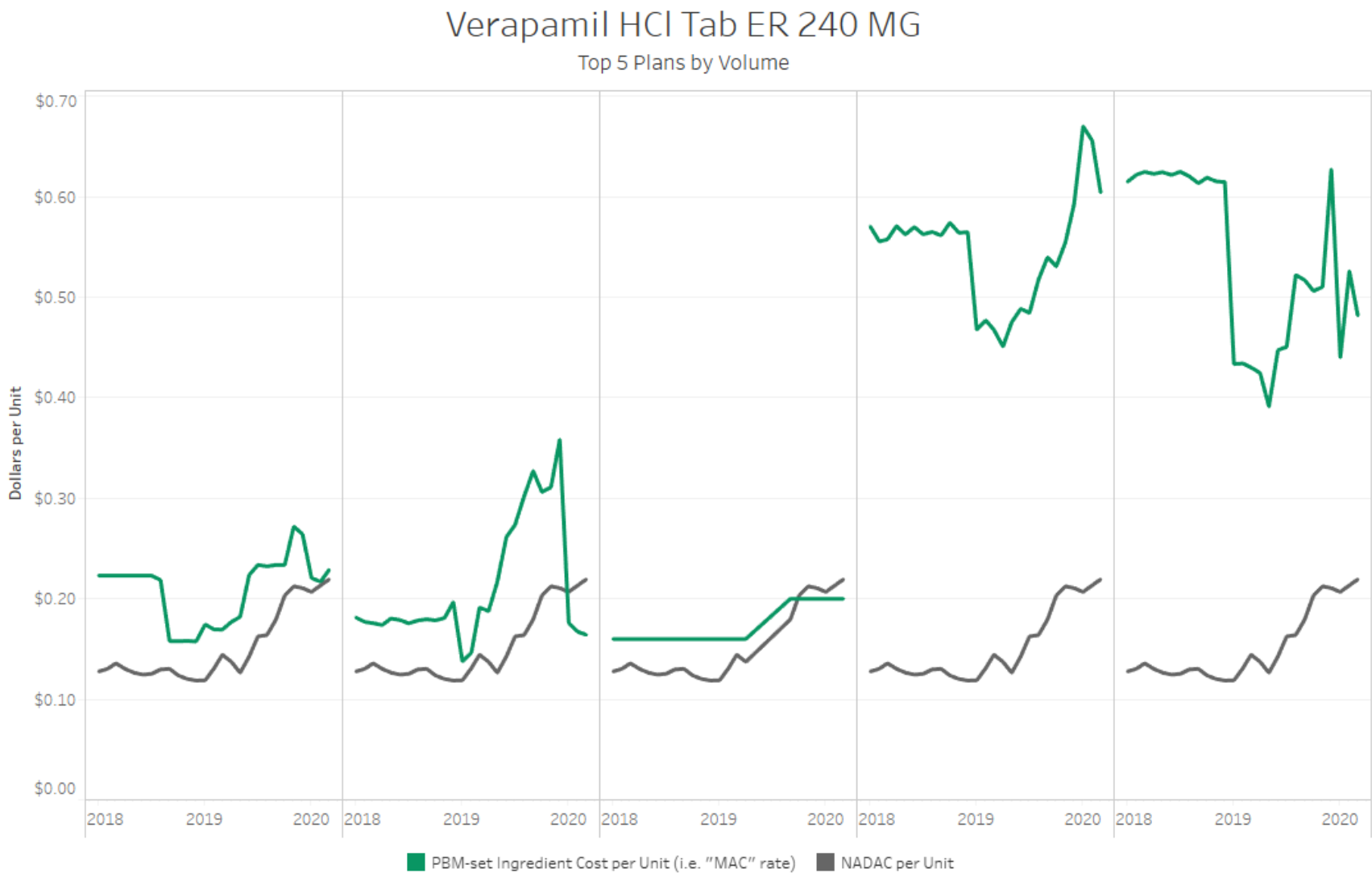


All PBM Ingredient Costs in this figure are limited to claims dispensed under a Basis of Reimbursement (NCPDP Field# 522-FM) equal to MAC (i.e. 6 or Ø6)



All PBM Ingredient Costs in this figure are limited to claims dispensed under a Basis of Reimbursement (NCPDP Field# 522-FM) equal to MAC (i.e. 6 or Ø6)

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