



THE CANCEROUS DESIGN OF THE U.S. DRUG PRICING SYSTEM

46brooklyn Research

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July 2018*

Of all the drugs in the U.S. marketplace, few have been as much of a topic of conversation as Gleevec, a popular medication for cancer patients. While the brand manufacturer Novartis was frequently criticized for its price increases during its exclusivity period, when generics entered the market, prices of those versions plummeted. But in analyzing CMS data, we found that even though prices were crashing, some state Medicaid programs were still being charged much higher prices. The data shows that there are serious flaws in the drug pricing system.

There are few things in this world that can be as life-altering as a cancer diagnosis. A diagnosis triggers a slew of events: planning, testing, appointments, therapy, and more. The physical toll is immense, and the strain on those who have to foot the bill for treatment is staggering.

Given the growing scrutiny on prescription drug costs and our collective interest in cancer treatment, 46brooklyn was drawn to the ongoing story involving the price of the popular cancer medication, Gleevec.

Here is this miracle cancer drug that has been off-patent (i.e. generic) for over two years now, so theoretically, the generic version should be yielding tremendous savings. But it isn't. For many, generic Gleevec still has an annual price tag equivalent to a luxury vehicle. Something didn't seem right, so we dove into public CMS Medicaid program data to see what we could find.

What we've identified is a serious flaw in how several states are managing prescription drug spending for generic drugs within their Medicaid programs, and we believe that what we suspect is that this could be occurring in non-Medicaid plans as well. While the price of generic Gleevec has been declining rapidly, we found that many state programs aren't seeing the savings, and in fact, **there are some states that are paying twice as much as other states.**

While this is just one prominent example of the inherent defects in our drug pricing structure, this isn't just a generic Gleevec problem – it's a fundamental problem with the system that was designed to manage our prescription spending.

This is 46brooklyn's maiden voyage into identifying the cancers of our drug pricing system, so let the diagnosis begin.

Generic Gleevec: The king of oral chemo agents

In 2017, the U.S. spent \$176.7 million on generic oral chemotherapy agents within its state Medicaid programs (Figure 1). Nearly half of this spending was on generic Gleevec (imatinib mesylate), despite the fact that it only comprised one percent of overall oral chemotherapy utilization. Said differently, generic Gleevec is 83 times more expensive than your average oral chemotherapy medication. You read that right. **Eighty-three times.** Clearly, the analysis of the oral chemotherapy agent segment starts and ends with one question – why is generic Gleevec so expensive?

This pricing movement did not go unnoticed. As Carolyn Johnson from the *Washington Post* expressed, “Instead of rising in sudden surges, Gleevec’s price crept inexplicably upward each year. When powerful second-generation drugs began to give physicians choices, Novartis raised the price even faster.”

Johnson also noted that while list prices rose, list price is not an accurate picture of the “net price” – the actual price paid by insurers or pharmacy benefit managers (PBMs) after rebates and discounts paid from the manufacturer back to the insurers or PBMs. In recent months, these rebates have come under fire from the White House, with senior officials seriously exploring eliminating them altogether due to their inflationary effect on list prices.

Rebate debate aside, pressure to reduce the economic burden on patients undergoing chemotherapy treatment was understandably mounting. At more than \$300 per tablet by 2015, patients and payers eagerly anticipated the release of generic forms of the drug to help lower the costs.

Given the stakes, speculation mounted on what would happen to the price as generic manufacturers entered the market.

Medicaid Oral Chemotherapy Annual Generic Spend

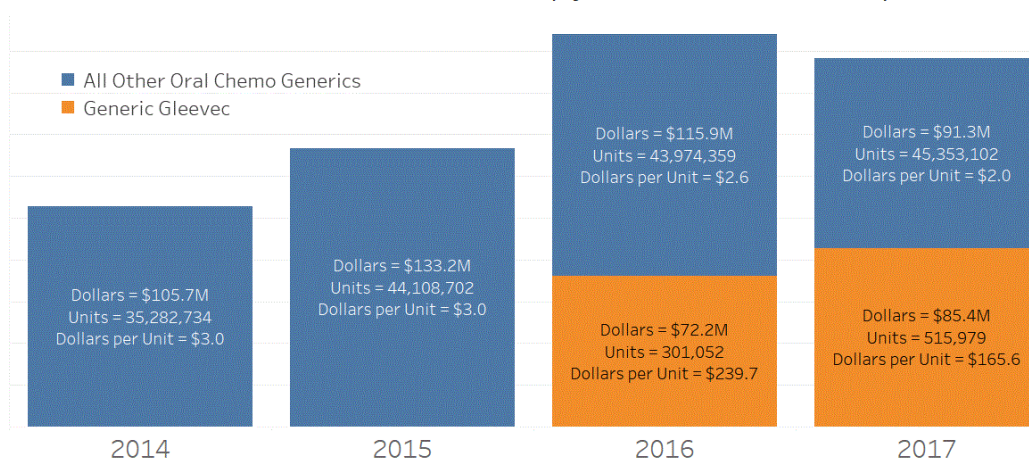


Figure 1
Source: CMS State Utilization Database; 46brooklyn

Before we attempt answer this question, we have to rewind back a few years to the days before the generic was introduced.

Novartis' Glee: The brand-only days

During its brand exclusivity period, Gleevec’s manufacturer Novartis was often criticized for its pricing. Using 46brooklyn's Drug Pricing Dashboard that tracks CMS's National Average Drug Acquisition Cost, commonly referred to as "NADAC," we can see the pricing movement of the drug over time. Towards the end of Novartis’s Gleevec patent, its list price rose around 10 percent every six months (see Figure 2).

Note: NADAC captures retail pharmacies’ reporting of what they are invoiced for drugs through wholesalers.

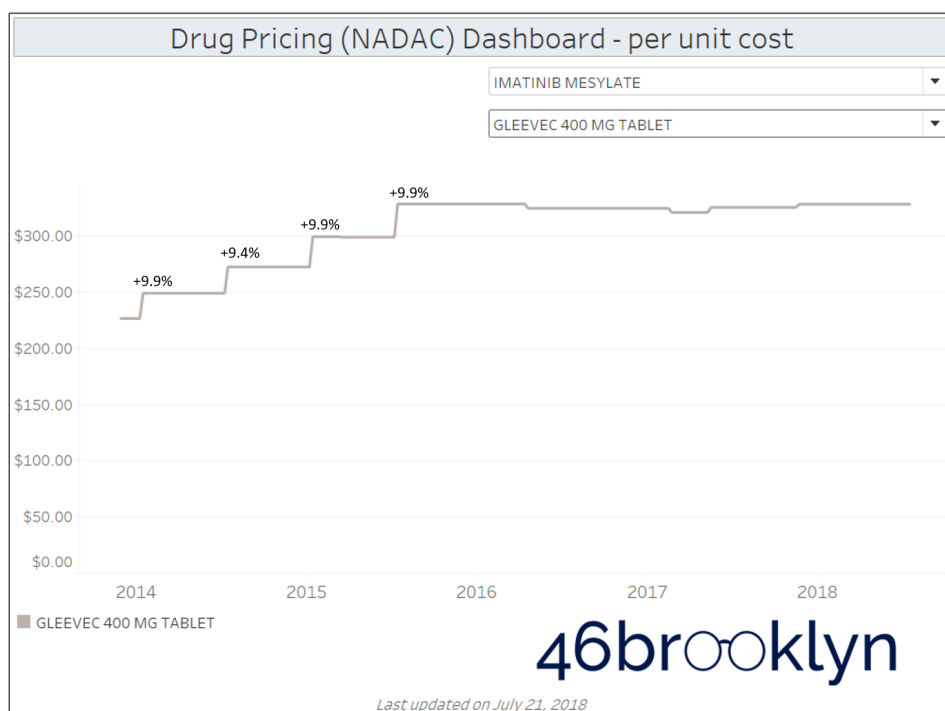


Figure 2
Source: CMS NADAC Database; FDA product/package tables; 46brooklyn

The generic comes to market

Generic imatinib mesylate was finally released by Sun Pharmaceuticals on February 1, 2016, starting a six-month exclusivity period that analysts estimated would be worth \$250-300 million in revenue for Sun. Then, as additional manufacturers entered the market, PBMs started to shift to the generic. In late 2016, PBM heavyweights CVS Caremark and UnitedHealth's OptumRx announced they would do just that.

"In situations where the medications are equivalent, from a medical point of view it makes sense to do this in order to reduce cost," Troyen Brennan, CVS's chief medical officer, told *Bloomberg*.

"As an organization dedicated to the delivery [of] high quality, cost-effective care, we are extremely excited about the recent approval of a therapeutically interchangeable generic form of imatinib (Gleevec) ... When coupled with what is likely to be a significant drop in pricing post-six month exclusivity, this agent will represent an enormous value to clients, providers and patients alike," said OptumRx chief pharmacy officer David Calabrese in a statement.



Fortunately, CMS tracks State Utilization Data, which confirms that generic utilization did ramp up quickly in 2016 (Figure 3). In 2016, the generic (400 MG strength) was responsible for 54 percent of all Medicaid Gleevec prescriptions dispensed, and this rose to 79 percent in 2017.

On its surface, the transition from brand to generic occurred just like it's supposed to, meaning that lower prices should be on the horizon.

Medicaid Gleevec Prescriptions Dispensed (Brand v. Generic)

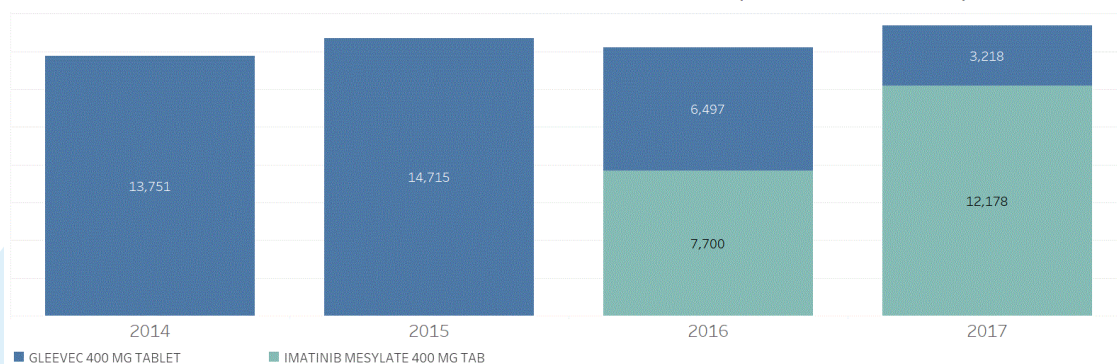


Figure 3

Source: CMS State Utilization Database; 46brooklyn

Look out below! Generic Gleevec deflation!

In March 2017, Dr. Hagop Kantarjian of the University of Texas MD Anderson Cancer Center, one of the original Gleevec trial leaders, told NBC News, “Two years from now, the price of generic imatinib in the United States (or purchased from abroad) will be significantly lower, hopefully less than \$1,000/year.”

This viewpoint might sound ambitious to those that don’t follow the generic marketplace, especially since the quote was uttered at the tail end of a quarter when the government paid \$236 per pill (\$86,400 per year) for imatinib mesylate 400 MG. But according to PBM giant OptumRx, “based on historical data, prices for generic versions can be reduced by as much as 90 percent once the total number of competitors reaches eight or more.”

The great news is that we are well on our way to this level of competition. Our 46brooklyn Drug Pricing Dashboard shows that there are now exactly eight different National Drug Codes (NDCs) of imatinib mesylate 400 MG, with eight different labeler codes, and at least six manufacturers. Using the same dashboard, we also found that OptumRx was spot-on with their assessment of supply and demand of generic drug pricing. Prices tend to drop like a brick once competition heats up. Generic Gleevec is no exception – competition has driven the June 2018 NADAC down to just \$33.46 per pill (\$12,213 per year), an 89 percent drop from when it was introduced in early 2016 (Figure 4). This should give us all hope that Dr. Kantarjian’s bold prediction for \$1,000 per year for generic Gleevec by March 2019 is still very much achievable.

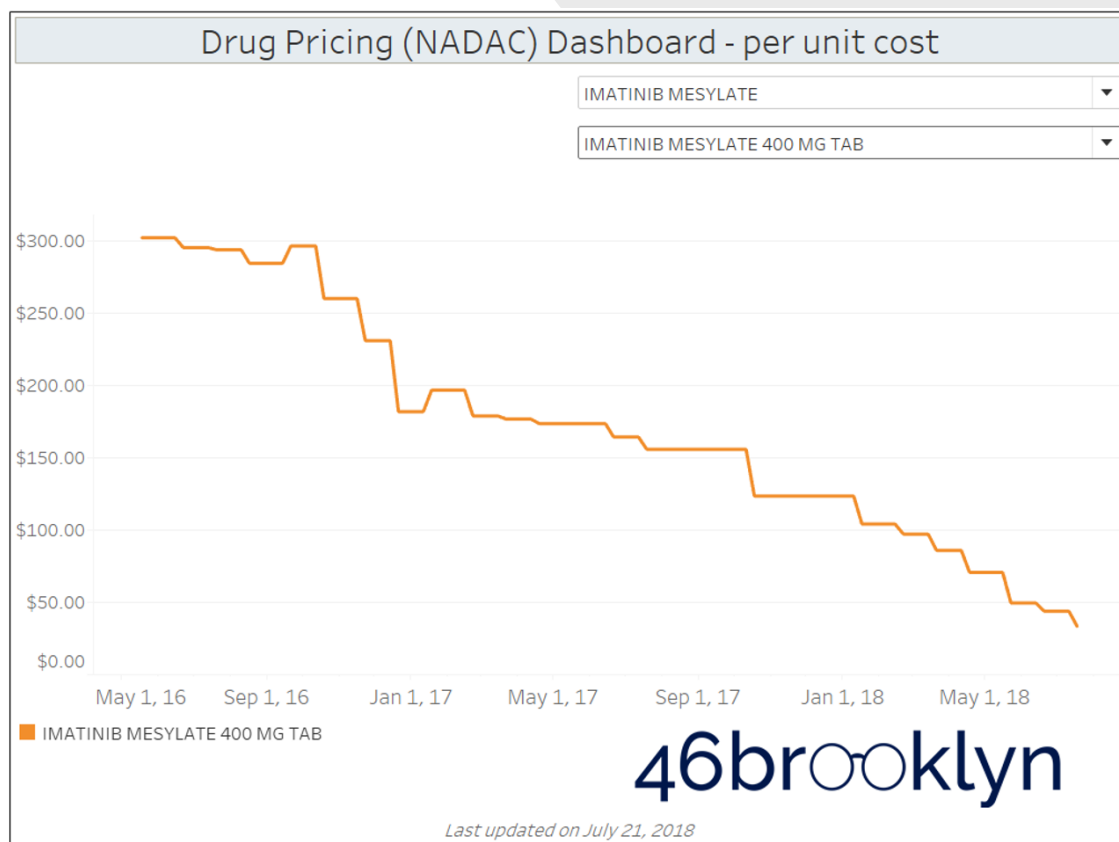


Figure 4

Source: CMS NADAC Database; FDA product/package tables; 46brooklyn

Don't celebrate yet... What we pay is not always based on what a drug actually costs.

So, the price of imatinib mesylate has plummeted nearly 90 percent. That means our costs are plummeting at the same rate, right?

Not so fast.

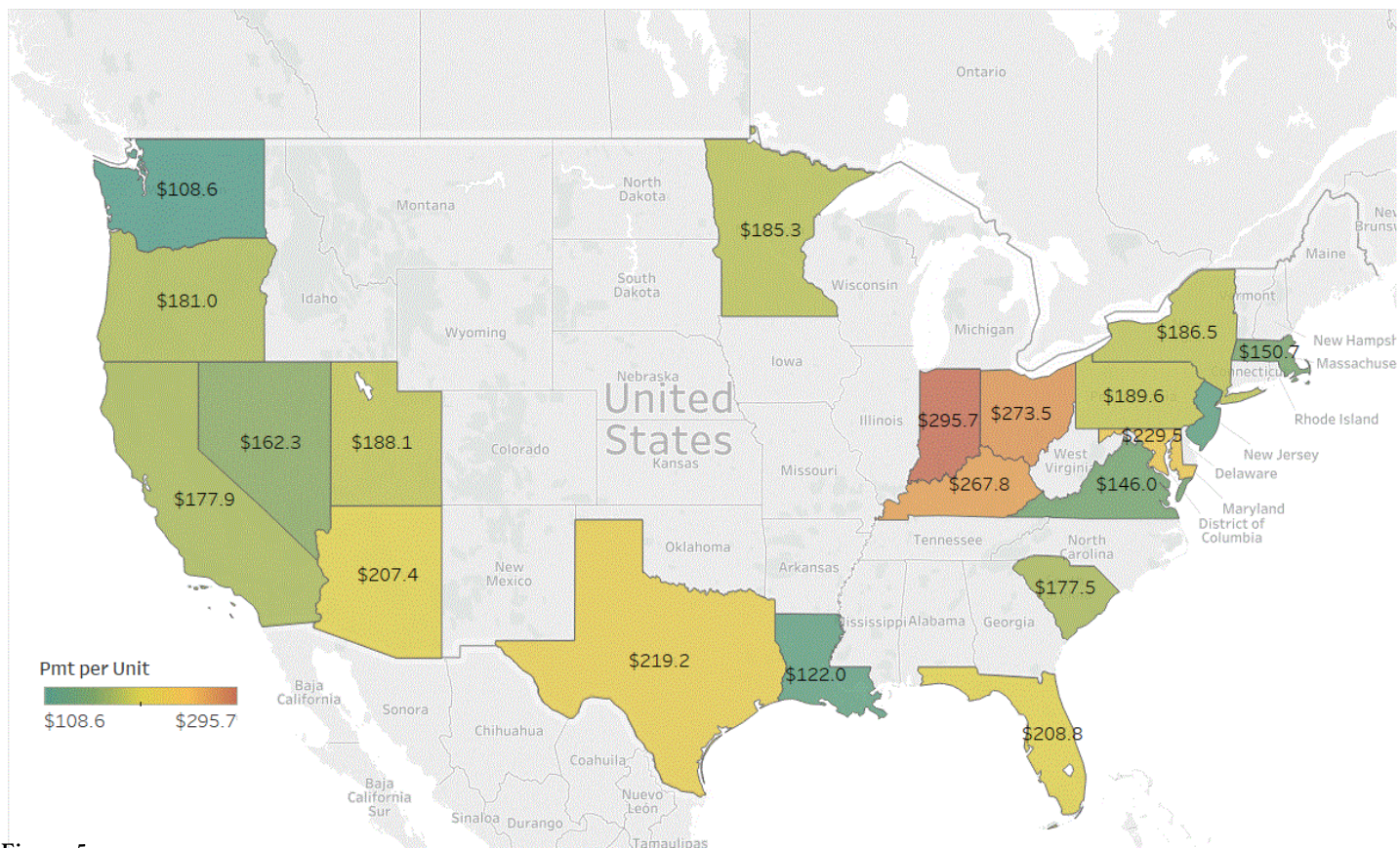
Stacie B. Dusetzina, Ph.D., associate professor of health policy at Vanderbilt University School of Medicine, recently told *HealthDay News*, “Most estimates of price reductions due to generic entry assume prices will drop by as much as 80 percent. Obviously, we aren't even close to that mark.”

Thankfully, by merging together the CMS State Utilization Database (states' reporting of what they pay for drugs through Medicaid) with the CMS NADAC Database, we can reconcile these two numbers. Using 46brooklyn Medicaid Drug Pricing Heat Map, we find out that many states are actually reporting generic Gleevec expenses within their Managed Care programs that are well above acquisition cost



of the drug (Figure 5). There is a staggering spread of what state Managed Care Medicaid programs are spending on this drug in the most recently reported quarter (Q1 2018). It ranges from \$108.60 per pill (\$39,639 per year) in Washington state to \$295.70 per pill (\$107,931 per year) in Indiana. That's right – same drug, same time, different state, way different price.

Payment per Unit Map (2018-Q1) IMATINIB MESYLATE 400 MG TAB - Managed Care 2018-Q1 NADAC = \$83.69



When we drill down into the states with higher cost generic Gleevec (such as Indiana, Ohio, and Kentucky) we can see the nature of the problem – the savings from generic deflation is not making its way to the state, or at least not to the data the state’s Department of Medicaid is reporting to CMS.

As you can see from Ohio Medicaid data (Figure 6), there is a massive difference between the average invoice costs of pharmacies and the rates being reported back to the state. With a gap this large (and implications that are pretty unsettling), of course our first concern was the quality of the data. But that concern was quickly alleviated when we looked at the historical trend charts for other state Medicaid programs like Managed Care in Washington state and Fee for Service in North Carolina.

Both of these programs are designed to reimburse on a cost-plus basis, with NADAC (at least in part) as the benchmark. So you would expect their payments to move in tandem with NADAC, and shown in Figure 7 and Figure 8, they do!

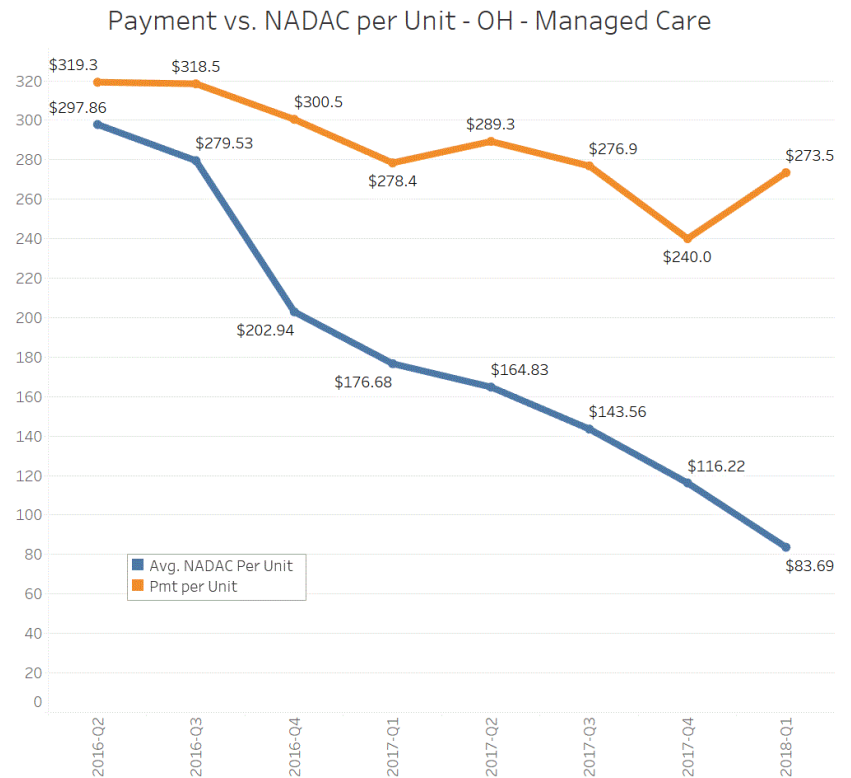


Figure 6

"That's right – same drug, same time, different state, way different price."

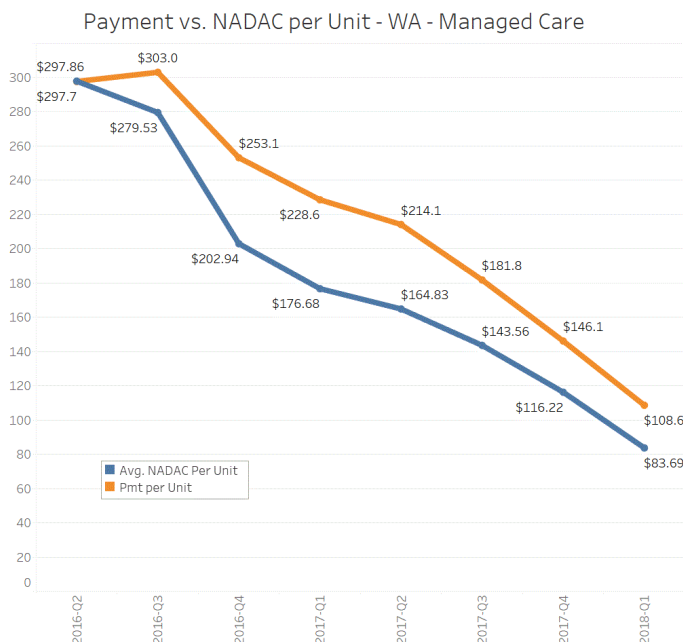


Figure 7

Source: CMS State Utilization Database; CMS NADAC Database; 46brooklyn

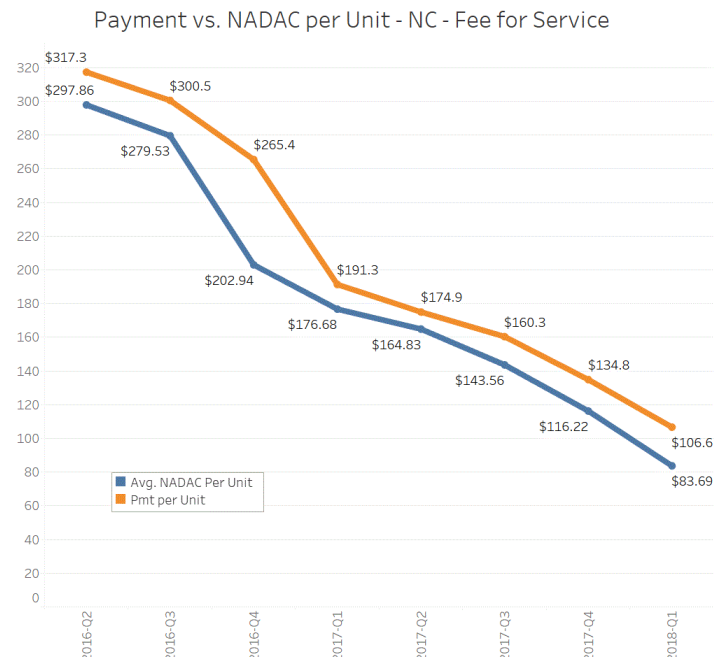


Figure 8

Source: CMS State Utilization Database; CMS NADAC Database; 46brooklyn

To spread or not to spread? That is the question.

With strong conviction in the data, our attention now turns to the Managed Care programs in states like Ohio, Indiana, Kentucky, and for that matter any other state that paid north of \$125 per pill for generic Gleevec 400 MG in Q1 2018 (which according to Figure 5, is most states).

Why are these states overpaying for such a high profile drug? The answer is that many state Managed Care Organizations (MCOs) have chosen to enter into non-transparent “spread pricing” contracts with their pharmacy benefit managers (PBMs), likely to save up-front administrative fees. Spread pricing in its simplest terms is the difference between what PBMs pay pharmacies and what the PBM then bills on the same transaction.

Once in this “spread pricing” contract, both the MCO and the state’s Department of Medicaid lose all visibility into what their underlying drugs actually cost, handing the keys over to the PBM to deliver on some predetermined overall cost target for the entire program – a target that likely never took into account the substantial generic deflation that was going on in the marketplace. Meanwhile, the PBM can effectively just sit back as generic prices plummet, knowing that it is under no requirement whatsoever to pass the full extent of those savings back to the MCO, and more importantly, the state.

Ohio learned this the hard way in 2017. The state recently completed a study showing that PBMs took a

spread of \$223.7 million in 2017, or 8.8% of gross drug spending. If you consider that the overwhelming majority of spread pricing is associated with generic drugs, the PBMs' share of gross generic drug spending has been estimated to be as high as 30%. The Ohio Department of Medicaid came under some heat from lawmakers after these numbers were released, but in fairness to them, they are likely just one state in a bucket of states that have been overpaying for generic drugs through their managed care programs, and now thanks to Ohio’s efforts toward transparency, we now know just how much money is on the table.

Staying with Ohio, there are two more interesting things to note. First, recall above that CVS Caremark and OptumRx both expressed enthusiasm for the release of generic Gleevec, alluding to the savings it would inevitably yield to payers and patients. In Ohio, these two PBMs are the only ones operating within the Medicaid managed care program. The second point is that these PBMs typically restrict access to these types of specialty medications to their own specialty pharmacies.

So in the case of generic Gleevec (and other pricey specialty medications), it is not unreasonable to assume that the majority of the gap between the NADAC and the State Utilization Data (shown in Figure 9) is in some way being captured by the PBM industry.

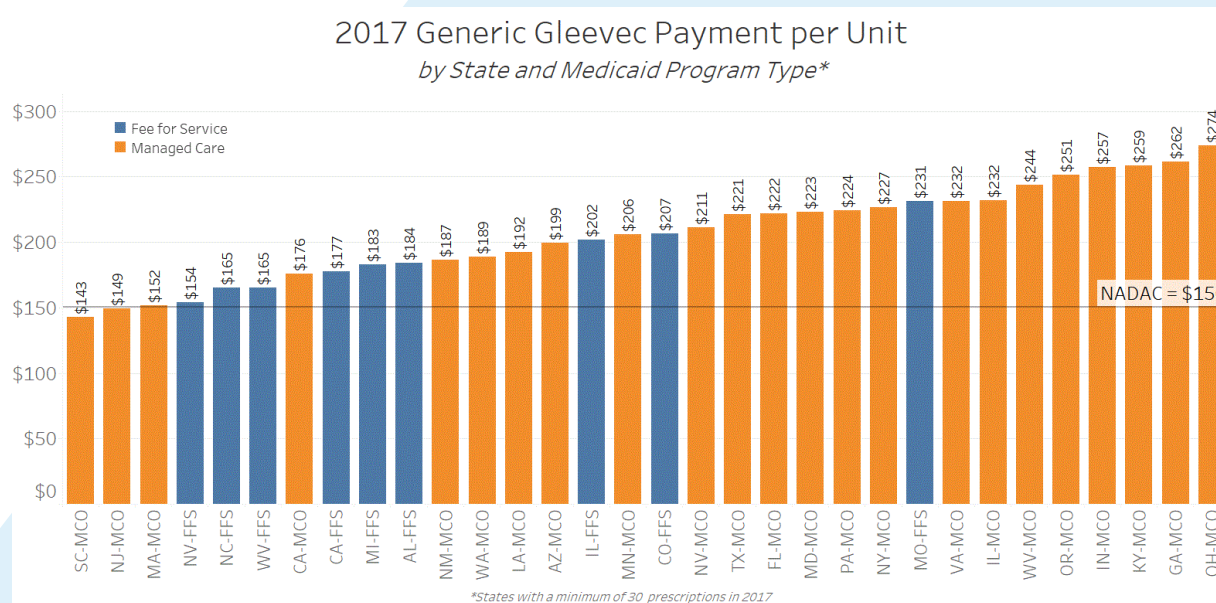


Figure 9

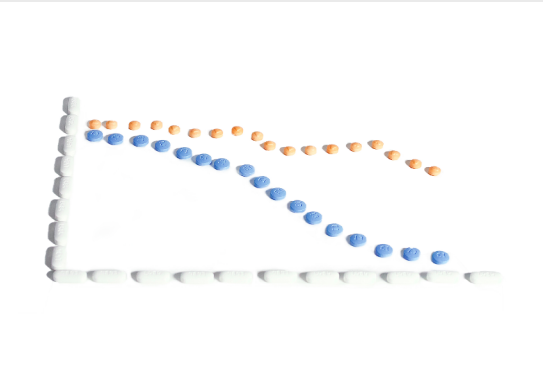
Source: CMS State Utilization Database; CMS NADAC Database; 46brooklyn

Putting generic "markup" in context

So the data is clearly telling us that "the price" Medicaid pays for a drug is clearly not THE PRICE of the drug. Moreover, the difference between these two – the markup – has been growing over time as THE PRICE declined (as our Economics 101 class said it should), while "the price" did not.

It's helpful to put the size of generic Gleevec markup in context. We figured that a relevant comparison would be to Novartis' heavily criticized brand-name Gleevec price increases during the last years of its patent exclusivity. We wondered, how did these brand price increases compare to the growth in generic markup?

To do this analysis we borrowed a concept from our finance textbooks called Compound Annual Growth Rate (CAGR). According to Investopedia, CAGR is "the rate of return of an investment over a certain period of time, expressed in annual percentage terms." So CAGR is a mechanism we can use to compare the annualized growth rates of Gleevec prices before its patent expired to annualized



growth rate in the markup of imatinib mesylate 400 MG after it went multi-source through Q1 2018.

Figure 10 is what we found. Imatinib mesylate markup in managed care rose by 281% per year since it went multi-source generic (from \$14.03 per pill to \$104.26 per pill over roughly 1.5 years), dwarfing the 20% annualized growth rate in Gleevec list price in the two-years prior to its patent expiration.

To be clear, we are not condemning nor condoning the price increases in brand name Gleevec. But does the average managed care PBM/specialty pharmacy really need to charge our Medicaid programs \$188 a pill for a drug that costs \$84 per pill? This makes the brand name inflation seem pretty tame in comparison.

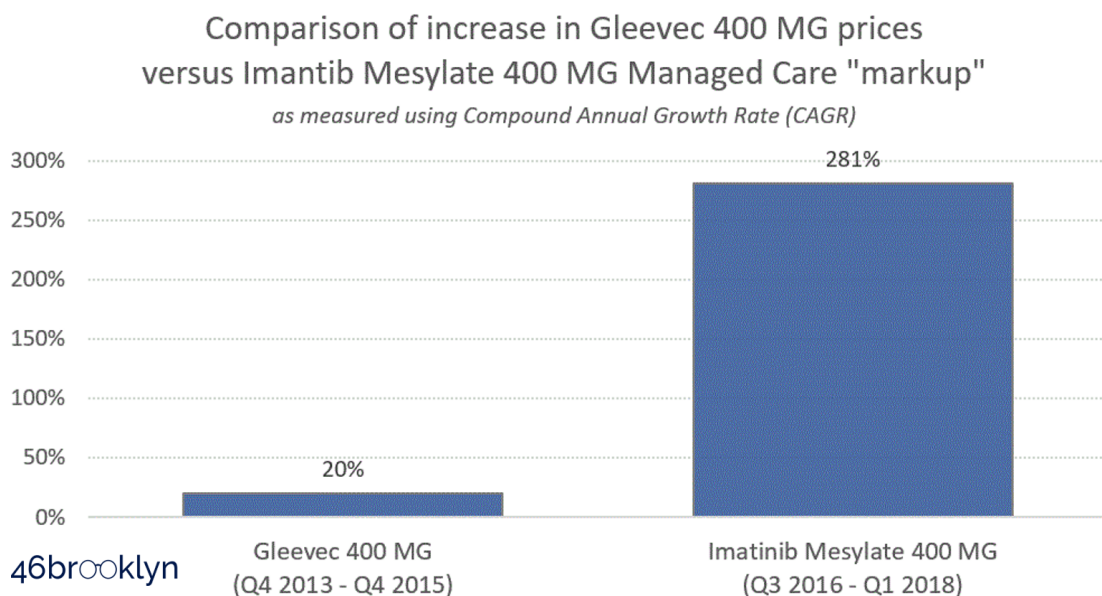


Figure 10

Source: CMS State Utilization Database; CMS NADAC Database; 46brooklyn

Can't trust "the process"

We know what the criticism will be to this analysis. This is one drug (albeit, a very important drug) out of a universe of thousands of generics. Clearly, we can't draw any conclusions from one drug, right?

Yes and no. Sure, a more comprehensive analysis spanning all generics would be helpful and (spoiler alert) we have done this already and have found similar issues with enough new/expensive generic drugs to strongly suggest that this isn't an anomaly. You can do this too using our Medicaid Drug Pricing Heat Map.

But leaving the argument there would be dismissing the core problem. Here we have the most heralded oral chemotherapy generic to come to market in at least a decade, and some states are paying more than three times its cost? Do we really want to endorse a system that has allowed this to happen, especially given that according to Dr. Stacie Dusetzina's research, there appears to be symptoms of the same types of pricing practices within commercial plans as well?

We're big sports fans here at 46brooklyn, which is likely what brought this anecdote to mind. In the National Basketball Association, the Philadelphia 76ers have a saying to "Trust the Process." We believe that a well-designed (and ideally simple to understand) process is essential for achieving the right results, the right way. Maybe this is our biggest problem with what we have found. The data tells us the process we currently have in place is complicated and opaque. If its goal is to lower health care costs for all of us, we have clearly found a flaw in this system. As such, it's hard for us to "Trust the Process." Maybe it's time for a new process.

