Medicaid Rebates and the AMP Cap Removal – Building Your Internal Analytics

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Staying on top of utilization trends is key in today's pharmaceutical market. Due to the numerous changes in the Medicaid Drug Rebate program, this is an area where many manufacturers have opportunities to enhance their current data analytics and tracking tools. With the Q2 Medicaid cycle now in the books, and on the heels of CMS issuing a final rule codifying the AMP cap removal, I thought now would be the perfect time to discuss some best practices for monitoring your Medicaid utilization. Running this analysis is critical for manufacturers with legacy retail oral solid products with URA in excess of WAC after the AMP cap removal. This is also important even if your drug is in a class where a competitor molecule is uncapped, because that competitor may cannibalize sales in future periods.

Market access/payer data is expensive, so in this article I am going to focus on publicly available data sets that you can obtain without having to purchase third party data. If you do have market access/payer data, you can still utilize these approaches and publicly available data sets, augmenting them with the data you purchase.

We are going to focus on the 5 steps you can take to enhance your analytics and tracking tools to stay ahead of any Medicaid changes from both a business and a finance accrual perspective.

1. Define Your Competitive Market

One of the first steps you should implement is to define your competitive market basket. In some markets, this may be as simple as a single branded (NDA or BLA) and a competing generic (ANDA) product; however, in many instances there are multiple products that treat the same disease. Establishing a market basket is a one-time initiative, but you should keep an eye out for any market changes – product discontinuations, new package introductions, or generic competition.

Your goal in developing a market basket is to create a series of benchmarks to isolate as many market access variables as possible. This will provide the foundation for your analytics. Since we are focused on Medicaid in this article, the drugs you should select are drugs that could possibly be moved into a preferred formulary position in your therapeutic class. A preferred formulary position will generally limit the "feedback loop" to physicians, preventing them from altering their prescribing behavior, especially in a crowded class. Other areas to keep in mind

when building your market basket is product form, cost and distribution model. When you are ready to set your market basket you should take the following steps:

- Research payer formulary lists – there are many plans that make their formularies and exclusion lists public. Typically, a Google search along the lines of "ESI national exclusion list" or "CVS national formulary" will quickly pull up the file that you are searching for. Once you have obtained the formulary or exclusion list, you can search for your product and see how PBMs are viewing you and your competitors. These entities will often have already grouped products for you, saving you time on background research.

- Research specific disease states – sites like drugs.com or a therapeutic class Google search will give you a jump start on alternative drugs. If you have a strong document repository and/or archive, you may be able to pull some of your launch materials, including your payer boards or possibly ICD10 codes. These materials will give you the market basket immediately. Once you have a few products identified, go and pull each product's Package Insert and read the "Indications and Usage" section. In it, you will find most of the therapeutic areas where the product is used, and where you should look for competitive products. I promise you won't need to be a scientist to figure this out. This portion of the research will generally be the most time consuming, because you want to be thoughtful in how you are grouping products. I generally advise manufacturers to keep a close eye on drug form here, as there can be material pricing and prescribing differences. Should you ever have any questions, don't hesitate to reach out to your Med Affairs or Regulatory teams. I have found that they normally have the answers to common questions about these data sets.

- Leverage the FDA website – the orange book, purple book and NDC directory can provide you with meaningful information on the package sizes, routes of administration, and number of competitors in the marketplace. This is typically the last search I do to define my market basket, to make sure I have not missed any competitive molecules.

2. Establish Your Thresholds

I review a lot of data models every week, and one of the common issues I see is not setting the proper thresholds for flagging changes. I often see only one or two of the following:

- a dollar-only impact threshold (e.g. only flag impacts greater than $1M)

- a volume impact threshold (e.g. highlight unit changes +/- 10,000)

- a percentage-based impact threshold (e.g. all changes +/- 10%)

Each one of these is important, but doesn't give you full visibility by itself. Your models should always include all three types of thresholds, so that you don't miss early warnings. This is especially critical in Medicaid analysis models, since changes rarely happen immediately. Generally, you will see gradual changes from state to state or quarter to quarter. If you don't have all three configurations built you may miss the incremental changes occurring quarter over quarter. Remember that these thresholds are only meant to provide early warnings. You will still need to use your judgment to determine if a change is worth further attention/analysis and sharing with the broader team.

Another key consideration in setting thresholds is establishing the comparison time frame. Having the proper time frame will minimize false alarms. When analyzing your Medicaid utilization, the I have found the following time frames will provide you sufficient coverage metrics:

- quarter over quarter (e.g. Q1 2024 versus Q2 2024)
- year over year (e.g. 2023 versus 2024)
- same quarter last year (e.g. Q1 2023 versus Q1 2024)

If you have an internal system or data mart, these types of analytics can be built into existing dashboards. Power BI is a great tool for these types of trends, but even a couple of quick Excel pivot tables paired with conditional formatting will yield effective results.

Lastly, when presenting findings, I typically recommend the use of PowerPoint, following this simple formula:

- Slide 1: the background and analytic goals.
- Slide 2: the model and data sets.
- Slide 3: the findings.
- Slide 4: the action items.

Specific to Medicaid, it is just fine to not have any urgent action items. There were many times when my action items were simply to continue tracking the trends quarter over quarter.

3. Review Your Program Utilization

When reviewing your Medicaid utilization, you will need to have the right Medicaid rebate history. If you don't have a system or data mart, you will need to spend the time to build your data set. You can leverage MDP as a shortcut. Once you log into MDP:

- Go to “State Utilization” and then select “State Data”.
- Enter your labeler code, the quarters you need, and click “Search”.
- Export the file into Excel to build your data mart.

Once you have the data set, your next step is to identify the trends in the data. I typically advise having at least 8 quarters of Medicaid data available. The reason to leverage 8 quarters is that it gives you enough time to implement the thresholds discussed in section 2 and analyze those results. Additionally, you will want to break this data down by state, program, and ROSI versus PQA. These data elements will give you the ability to run the sub-metrics inside each respective state and program.

When I am reviewing Medicaid data, I am generally concerned with three areas: rebate dollars, units dispensed and scripts. The first question I am attempting to answer is, “Are my rebates paid in line with my calculated URA?”. Here I am looking for consistency between rebate dollar trends and the calculated URA trends, controlling for the units. An additional step for products impacted by the AMP cap removal, is to always know how much of the rebate is driven by the standard URA, and how much is driven by the additional URA . The two main levers under your control may be the Best Price, which typically drives the standard URA calculation, and WAC – a WAC reduction can reduce AMP and the additional URA.

The second question I am attempting to answer is, “How have my units dispensed and scripts grown over the previous period?”. When you start your trend analysis around units and scripts, you will want to first determine how long a typical script is written for. Is it a 30-day script, a 90-day script or somewhere in between? You may need to request or download Medicaid CLDs to get at this. The relationship between units and scripts is informative. If you see a spike in units but not scripts, it could mean that patients are simply seeing a change in the amount of product they get; a proportionate increase in both units and scripts, on the other hand, indicates an influx of new patients. New patients should lead to increased sales as well as increased rebates.

Don’t forget to check in with your commercial team, specifically your account managers. You want to ask them if they have any contracting initiatives with specific states or state pools (e.g. NMPI or TOP$), as this will direct you to programs where you are more likely to see changes. This step can help you identify things to look for in formulary coverage (discussed below in step 4) that could influence how many Medicaid scripts are approved and ultimately generate a rebate.

4. Know Your Formulary Coverage

This is not the easiest step to operationalize, but if you stay on top of it, you can build an extremely powerful and informative data set. Both MMIT and Fingertip (to name a few) have

paid tools that provide detailed information around formulary coverage. Fingertip also has a free web version that you can leverage for research when you don't have access to paid tools. Once you sign up, you can use this tool to identify your product and your competitor's products coverage. You have the ability to monitor Commercial, Medicaid and Medicare programs and search where the products you selected are positioned. Specific to Medicaid, select the states that you identified in step 3, so that you can overlay this data with the utilization data. I recommend you search your formulary coverage twice a year, January 1 and July 1. Most formularies will update in January, but I have seen some Medicaid formularies update on July 1. A formulary change normally drives utilization changes, by affecting copay and utilization management conditions (e.g. step edits or quantity limits).

If you checked with your commercial team in step 3, you may find different formulary positions state by state. If you have a contract initiative or supplemental rebates being paid, then you should be looking for the Tier 1 Preferred formulary position in those states. Typically, any manufacturer that signs the National Drug Rebate Agreement should not see anything worse than the Tier 3 Non-Preferred position. If you do notice anomalies or changes in your products' formulary coverage, you should add this to your action items and have the commercial team reach out to find out what is going on.

A quick bonus note around formulary coverage. The Kaiser Family Foundation publishes a well researched annual report on commercial coverage for the US market. Make sure you are paying attention to Section 9 in this report, as it helps you communicate what those formulary positions actually mean to the patients' out of pocket costs, as well as the potential GTN impacts due to copay and buydown programs you run. Keep in mind that Medicaid is ineligible for copay and buydown patient programs, so you won't need to factor those into the Medicaid portion of the GTN.

5. Monitor Your 867 Data

The final step in building your analysis is incorporating complementary data sets, such as the 867 data. The goal here is to get an early indication if any state has made a formulary update affecting patient fills. Most likely, this type of change will result in local pharmacies altering their purchasing, which will drive changes in wholesale orders. To validate this type of change, you need the 867 data. Due to lags in Medicaid data, the 867 data will give you a more real-time view. Ex-factory sales data, on the other hand, is at too high of a level to know if changes are happening in a specific state, since it only shows bulk ordering by your distribution partner, and not downstream purchasing.

If you are not familiar with the 867 data set, there are a few things to know. This data is always available from your distribution partners, covered by the distribution service fees you pay, and typically itemized in the distribution service agreements. The 867 data is submitted through an EDI interface, so it is generally not usable without some type of data conversion. Most 3PLs (e.g. Cardinal SPS) or other third-party channel data aggregators provide you this data in a

usable format. If you don't know where this data lives, you can normally email your trade team, and they will direct you to the right place.

Once you have the data available, you want to see if any of the downstream customers are showing ordering changes. For example, are the Walgreens pharmacies now receiving more product from the respective wholesaler? If you notice an increase in pharmacy ordering, say in New York, it could indicate that NY has made a formulary change, and now more patients are able to fill their Medicaid prescriptions. Remember, this is just a hypothesis, and you will need to incorporate the analysis from steps 3 and 4 above to confirm potential changes. Typically, you will want to analyze at least 8 weeks of ordering trends before making any judgment calls. Additionally, you can compare the current 8 week period to the previous year's 8 week period, as this will show if this trend is new or consistent. It is very important to account for seasonality in purchasing, as well as month or quarter end purchasing. Something that looks like a new trend may have been happening every year.

Closing Thoughts

Good luck in building your Medicaid analytics! I hope this information helps provide some clarity to your process. I want to leave you with a couple of additional thoughts.

Remember that the government (state and federal) does not move at the same pace you do. Sometimes, as manufacturers, we think that the states are going to immediately review every drug, class and category, and immediately optimize them. They won't. They are most likely to look at spend and utilization and then make decisions from there. This matters, because if your drug is not impacted today, it doesn't mean it won't be impacted tomorrow.

Another thing to keep in mind, especially when dealing with generic competitors, is that the "downstream" market is set up to dispense generic drugs instead of branded drugs. There are numerous states that have AB rated generic switching as a common practice. Pharmacies typically make more money dispensing a generic drug than a branded drug. These are complex topics, but something for a branded manufacturer to keep in mind, because even significantly higher rebates do not mean your product will be both prescribed and dispensed.

Lastly, don't overestimate prescribers' and PBMs' ability to drive changes. Physicians are unlikely to "DAW" specific molecules for their Medicaid patients. PBMs are unlikely to NDC lock competitor and generic drugs to maximize rebates for Medicaid eligible patients. There are exceptions to every rule, and drug cost and class do matter, but these are uncommon scenarios.

If you would like to discuss any of these takeaways or your Medicaid analytics, I am always happy to jump on a call or respond to questions over email. Don't hesitate to click over to the contact us section of our site or message me through LinkedIn.