Excelsior Solutions

2nd Quarter 2023

Newsletter

This Quarter's Articles

Humira Remains Top of Mind, but the Reason for That May Be Changing

Robert Kordella, RPh

How Does AMP Affect Drug Pricing?

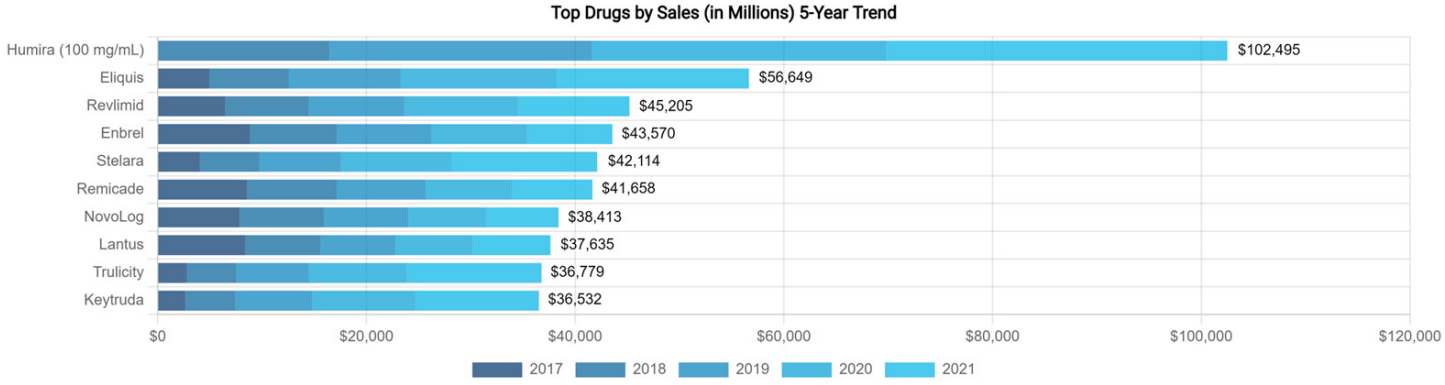
Greg Bigwood, FLMI

Pharmacogenetics: The Future of Prescribing?

Hope Nakazato, PharmD

Humira Remains Top of Mind, but the Reason for That May Be Changing

Together we have been talking a lot about the launch of the first biosimilar versions of Humira (adalimumab) this year – Amjevita having launched earlier in 2023, with several more versions expected on or around July 1, 2023. The reason for that is that Humira is, and has been, the proverbial "elephant in the room" since it has been the most expensive drug in most pharmacy benefit plans for several years. As the graphic from our data partners IPD Analytics below illustrates (used with permission), public, private and self-payers in the United States spent over $100 billion (before rebates) on Humira between 2017 and 2021.



IPD Analytics. Data STACK. | Sales, Discounts & Rebates. 5/30/2023.
https://www.ipdanalytics.com

That amount of spending has, justifiably so, focused most of our attention on the unit costs of Humira, and how much less we might expect to pay for a biosimilar alternative version of adalimumab. For example, even a 25% reduction in that $100 billion+ 5-year cumulative cost shown above would amount to a material amount of savings. But even that material savings is only part of the story, and the other part of the story is still unfolding.

Total cost is a function of unit cost multiplied by volume, and volume for our purposes means the number of prescription claims processed. In an odd twist to the old joke, "If a tree falls in the woods and there is nobody there to hear it, does it make a sound?" we might similarly ask, "If the unit cost of adalimumab falls dramatically but there is nobody left taking adalimumab, will you derive any savings?"

AbbVie is the manufacturer of Humira, and they also manufacturer two other products (among many others) that we can consider to be "successors" to Humira. Their names are Rinvoq and Skyrizi. I will not bore you with pharmacists' jargon about how their respective mechanisms of action differ, but you will be interested to see how their FDA-approved indications compare, and why we feel comfortable referring to them as successors to Humira. These are their respective FDA-approved indications as of today, but label extensions for existing products occur on a dynamic basis.

CONTINUED >>

COMPARISON OF FDA-APPROVED INDICATIONS (AS OF 5/30/23) WITH LOSS OF EXCLUSIVITY ("LOE") DATES

Indication	Humira (LOE already occurred)	Rinvoq (LOE October 2036)	Skyrizi (LOE February 2036)
Ankylosing Spondylitis	✓	✓	-
Crohn's disease	✓	✓	✓
Hidradenitis Suppurativa	✓	-	-
Polyarticular Juvenile Idiopathic Arthritis	✓	-	-
Psoriasis	✓	-	✓
Psoriatic Arthritis	✓	✓	✓
Rheumatoid Arthritis	✓	✓	-
Ulcerative Colitis	✓	✓	-
Uveitis	✓	-	-
Atopic Dermatitis	-	✓	-
Non-Radiographic Axial Spondyloarthritis	-	✓	-

CONTINUED >>

A recent article detailed how AbbVie spent ~$100 million on advertising in the first calendar quarter of 2023 supporting Rinvoq and Skyrizi with "ask your doctor" themed ads, and we have confirmed through industry sources that the AbbVie field sales team is touting the benefits of Rinvoq and Skyrizi over Humira to prescribers. Sometimes called a "switch pitch," this tactic involves touting the nominal clinical benefits of a successor patent-protected product as a defense against market share erosion of an older product facing generic or (as in this case) biosimilar competition.

In our own book-of-business data, we can identify material increases in the ratio of total Rinvoq-to-Humira claims and total Skyrizi-to-Humira claims between 1Q22 and 1Q23. For Rinvoq, that ratio went from 6.5% in 1Q22 to 9.8% in 1Q23, and for Skyrizi it went from 5.3% in 1Q22 to 8.6% in 1Q23.

Our caution to prescribers is for them to avoid succumbing to attractively packaged switch pitches without weighing the clinical and cost ramifications, especially for long-stable, long-thriving Humira patients. If Humira has been the best drug for certain patients for 10 to 20 years, then replacing it ought to require a compelling clinical argument to outweigh the material cost difference between biosimilar adalimumab and patent-protected Rinvoq or Skyrizi.

Robert Kordella, RPh, MBA
Senior Vice President and Chief Clinical Officer

Bob has more than 35 years of diverse experience in the pharmacy industry. Over the course of his career, Bob has led clinical and PBM operations teams in successfully managing more than $4 billion in annual drug spend. This was also while limiting per-member-per-year spending growth to levels that have simultaneously drawn industry acclaim and consistently high levels of member and payer satisfaction.

How Does AMP Affect Drug Pricing?

First, what is AMP? The average manufacturer price is a benchmark used by the Centers for Medicare and Medicaid Services (CMS) to determine Medicaid reimbursement for prescription drugs. Historically, the AMP has played a critical role in determining pricing by serving as the basis for calculation of Medicaid rebates but has rarely directly impacted employers. The Medicaid rebate is calculated based on a percentage of AMP plus an inflationary amount. The Affordable Care Act (ACA) of 2010 capped the total statutory Medicaid rebate at 100% of AMP even if the manufacturer continues to take price increases exceeding the rate of inflation. This allowed price increases by manufacturers without having to raise the rebate paid to Medicaid plans. However, this cap ends on January 1, 2024, under a provision of the American Rescue Plan Act of 2021. With this change, manufacturers may be required to pay rebates to the Medicaid program that exceed the list price of the drug. In other words, manufacturers may have certain drugs for which they pay Medicaid to use the product(s). This creates a new liability for drug manufacturers that did not previously exist.

Manufacturers then must decide whether to absorb or mitigate the new liability caused by this higher rebate. Our expectation is that many manufacturers will not absorb this additional cost but will make changes to drug pricing to reduce the rebates paid to Medicaid. We have already seen this with Eli Lilly, Novo and Sanofi, who have all announced substantial drops in wholesale acquisition cost (WAC) for certain insulin products. We expect additional manufacturers in other drug categories to take similar actions to avoid AMP cap exposure.

Although these actions are spurred along by regulations targeted toward Medicaid reimbursement, they also have an impact on employers and members. The change in WAC price will create a lower cost for members and plan sponsors at the point of sale but also have a material impact on rebates. Contract terms in nearly every PBM contract will be revised due to this change. Excelsior Solutions will work with clients and PBMs to ensure that all changes are economically neutral to clients.

Greg Bigwood, FLMI
Senior Vice President and Team Lead

Greg possesses over 20 years of diverse healthcare experience. Having spent several years in pharmacy benefit management (PBM) finance and underwriting, his deep understanding of PBM financials and operations ensures that his clients receive and maintain significant financial savings backed by unparalleled levels of service.

Pharmacogenetics: The Future of Prescribing?

The world of medicine is quickly progressing to cure previously untreatable viruses, prolong chronic diagnoses, and extend quality of life for many conditions. As more novel molecules enter the testing pipeline, a question remains about existing treatment populations and why some areas of care have not advanced as much as others. Although treatment guidelines have been well established for disease states that focus clinical diagnosis on objective metrics, should there be more individualization for others with low treatment response rates?

The global COVID-19 pandemic brought to light a population with increasing disease prevalence. Major depressive disorder (MDD) affects over 17 million adults in the U.S. alone, reaching a disease prevalence of about 7.1%.[1] With the additional stress load of the pandemic, rates nearly tripled and impacted an all-time high of nearly 1 in 3 adults.[2] MDD is often characterized by persistently low or depressed mood, decreased interest in pleasurable activities, feelings of guilt or worthlessness, lack of energy, poor concentration, appetite changes, slowing/hampering of mental or physical activities, sleep disturbances, or suicidal thoughts.[3] In addition to individual impact, MDD was ranked in 2008 by the World Health Organization as the third largest cause of disease burden on a worldwide scale, with projections of being number one by 2030.[3] Over the 8-year time period from 2010 to 2018, MDD prevalence increased in the U.S. by 12.9%, and the economic burden jumped from $236.6 billion to $326.2 billion annually. MDD carries a substantial price tag and extends beyond direct disease-state costs with a cost breakdown of 35% to direct costs, 4% to suicide-related costs, and 61% to workplace costs.[4]

Increasing MDD prevalence as well as the increased use of medication therapy has resulted in a nearly 400% increase in the rate of antidepressant use in the U.S. over the past 20 years.[5] With increased awareness and more prescribing, have we gotten better at treating this mental condition? With the leaps and bounds that have taken place in the optimization of guidelines for many other conditions, prescribing for MDD has remained constant with first-line medications being individualized based on symptoms, age, gender, ancestry/ethnicity, and drug interactions. With inconclusive information regarding any individual antidepressant's clinical superiority, all FDA-approved antidepressants are considered as potentially appropriate for first-line treatment.[6] Although there is individualized review of many subjective factors prior to starting a treatment, the current guidelines have an astonishingly low response rate. Only about 1 in 4 individuals with depression will reach full remission in a first medication trial.[7]

Integrating pharmacogenetics to guide antidepressant therapy has had promising results for treating depression. Pharmacogenetic testing (PGx) for this class of medications has now led to the identification of 32 gene-drug pairs having the rank of "high or moderate" evidence by two major research groups to support further testing. This proposed PGx testing is a simple saliva test, and focuses on four enzymes (CYP2D6, CYP3A4, CYP2C19, and CYP1A2) that impact the metabolism and breakdown of many of these psychotropic medications.

CONTINUED >>

Targeted identification of predicting how a particular individual will respond to a medication has shown promising results in many studies. A study in Canada found patients with MDD using treatment guided by PGx tests and recommendations had superior symptom improvement and higher response rates, being more likely to reach remission than those receiving standard treatment without PGx guidance. Additionally, a meta-analysis study from 2018 found that patients who used PGx to guide treatment were nearly twice as likely to experience symptom remission, compared with those who received standard treatment without PGx guidance.[7]

Given the devastating impact of MDD for the individual and for the surrounding ecosystem, it seems that PGx integration could serve as a viable option to improve the existing standard of care. Although PGx testing shows promise, many of the research studies lacked proper randomization or statistical power. While PGx appears to play a role in determining optimal dose and tolerability for patients, there are cost and time barriers that exist to integrating this process as a standard of care. Additionally, it remains to be seen if PGx tests can accurately predict the best therapeutic agent based on patient genetic sequence. As MDD prevalence and disease burden progress and increase, it will be interesting to see the impact that PGx will have on guiding future treatment success rate, economic burden, and patient quality of life.

Hope Nakazato, PharmD
Pharmacy Solutions Consultant

Hope is a pharmacy solutions consultant for the People Solutions Practice in Lockton Northeast's Washington, D.C., office. She is responsible for optimizing the pharmacy benefits of clients, bringing subject matter expertise to the forefront of client discussions to control pharmacy-driven trends. She also educates client teams on pharmacy market trends, presents insight into trend drivers for account management, and provides solutions for managing year-over-year costs.

[1] Depression Statistics — Depression and Bipolar Support Alliance (dbsalliance.org).
[2] Depression Rates in US Tripled When the Pandemic First Hit — Now, They're Even Worse | The Brink | Boston University (bu.edu).
[3] Major Depressive Disorder — StatPearls — NCBI Bookshelf (nih.gov).
[4] The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018) — PubMed (nih.gov).
[5] Is increased antidepressant exposure a contributory factor to the obesity pandemic? — PMC (nih.gov).
[6] Clinical Practice Review for Major Depressive Disorder (adaa.org).
[7] Pharmacogenomic Testing May Help Achieve Better Patient Outcomes, Reduced Toxicity | Psychiatric News (psychiatryonline.org).