Are Formulary Exclusion Lists Aligned or Contrary to the Shift to Value-Base Care?

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The use of formulary exclusion lists continues to expand, with clear impacts to the perception and use of all related medications. Annual updates to these lists suggest a need for careful evaluation by benefit sponsors, clinicians, patient advocacy groups, and the pharmaceutical industry to determine implications on treatment outcomes and achieving value-based care.

In what is becoming an annual event anticipated by pharmacy plan sponsors and manufacturers, the largest two pharmacy benefit managers (PBMs), Express Scripts and CVS Health, recently published their initial announcements on pharmaceutical products they will be excluding from coverage in 2018. Their decisions create a ripple effect on employer benefit coverage, prescribers, and patient access to treatment. Last year, we commented on the exclusions announced for 2017, including potential implications in key therapeutic areas. This year, we comment on the 2018 exclusion lists, while assessing any year-over-year or future trends of note. As with previous years, the number of excluded products has increased, and new areas have been impacted. **Figure 1** illustrates the growth in the number of products noted as excluded based on the initial information released by Express Scripts and CVS Health in early August.

While the growth in the number of products excluded continues its double-digit percentage increases, our most notable observation is the number of products that have flipped between excluded and not excluded over the past 2 years. For example, CVS Health's list suggests 17 drugs that were excluded in 2017 will not be excluded in 2018.

One of the major differences between the announced exclusion lists is in diabetes treatment. Express Scripts has made very few changes to exclusions in this category over the past 3 years, whereas CVS Health continues very active management, with five changes for 2018. It is not surprising that CVS Health continues to target diabetes therapies, since it identified the class as one of the top contributors to brand inflation in 2016. As it continues to address this trend, CVS Health reversed last year's exclusion of Invokana by moving it into a preferred position, while excluding Jardiance from coverage. This move raises some questions. Cardiovascular outcomes data between the two drugs are similar, yet recent results from the CANVAS trial indicate a greater risk of amputation with Invokana. With nearly identical pricing, this action suggests a decision driven by rebate offers.

Other notable shifts in the exclusion lists include the continued support for biosimilars. Express Scripts added Neupogen to the list this year, while CVS Health maintained its exclusion of the drug from the prior year. Additionally, the continued exclusion of Lantus by CVS Health suggests the value of its follow-on biologic, Basaglar, was realized. Whether that was solely due to uptake of Basaglar or included additional price concessions would be of interest.

Lastly, both CVS Health and Express Scripts noted they are continuing to review hepatitis C and autoimmune/inflammatory treatments for potential action. The recent launch of a new treatment for hepatitis C and multiple agents in the anti-inflammatory market likely require more time to review—and negotiate discounts—before final decisions can be made in these classes.

INSIGHT CONSIDERATIONS

The competitive impact of products launching with a significantly lower price, based on whole acquisition cost (WAC), is being felt. PBMs, known for pursuing aggressive rebate dollars that support their revenue streams, are signaling a shift toward products with lower prices that deliver comparable clinical effects. Express Scripts' exclusion of Forteo, a higher-cost alternative to newer agent Tymlos, coupled with its exclusion of Neupogen in favor of the biosimilar Zarxio, provides some baseline evidence for this claim. Certainly rebates will continue to remain a significant factor, but lower-priced alternatives are gaining greater consideration. Making such moves in favor of price concessions could prove beneficial at first glance, as WAC products may garnish increased share due to exclusions of higher-cost products.

"SENSITIVE" THERAPEUTIC AREAS

Some prior exclusions within more sensitive therapeutic categories underwent reversals in the 2018 update. CVS

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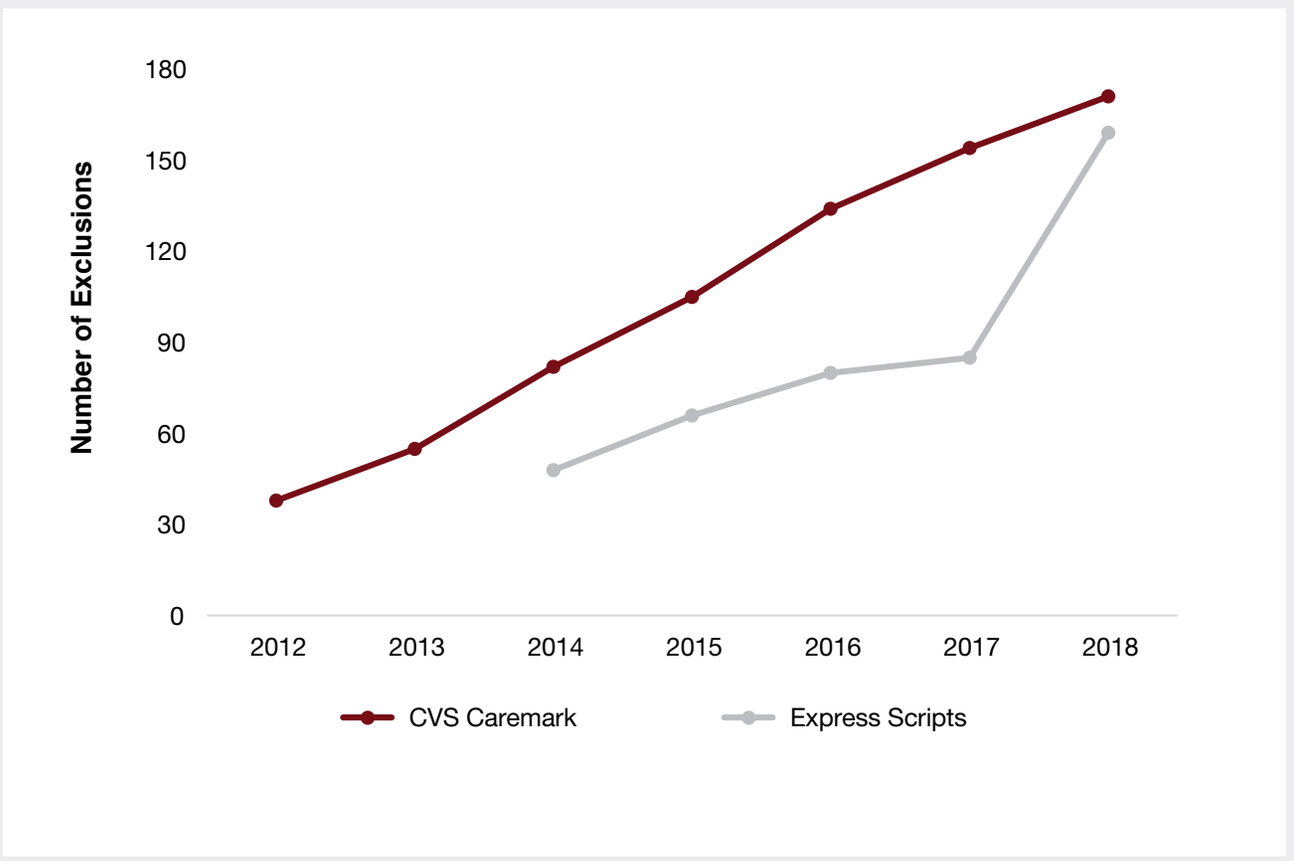

Figure 1. Formulary Drug Exclusions by Year

Health reversed exclusions for popular drugs in prostate cancer and multiple sclerosis. As noted earlier, aggressive competitive responses may have contributed to the exclusion reversals; however, strong patient and provider advocacy or demand carries added weight when dealing with more sensitive drug classes. Because of these reversals, the extent of exclusionary management of oncology and multiple sclerosis treatments remains low. Possibly, as biosimilars come to market and leading branded oncology agents lose their patents (eg, Gleevec), a more traditional exclusion approach will prevail: targeting brands with generic or biosimilar alternatives.

REBATE CONTRACTING

The pharmaceutical pricing debate is as strong as ever. Turing Pharmaceuticals' 5000% price increase of Daraprim and Mylan's 600% increase for its EpiPen since 2009 have elevated the drug pricing debate to unprecedented levels. Furthermore, politicians across all parties have criticized pharmaceutical manufacturer pricing strategies and have looked toward policy and regulations to curtail steep price hikes. As a result, payers are leveraging exclusion drug lists to negotiate steeper rebates and "penalize" (if you will) pharmaceutical manufacturers for egregious pricing tactics.

Contracting, however, may not be enough. Because of the complexities around rebate sharing, consumers may not realize the full extent of contracted discounts, and payers are ultimately faced with having to explain high-cost drug selection in favor of a lower-cost alternative that is clinically comparable. The foreseeable future indicates that payers will continue to leverage and tweak exclusion drug lists to demonstrate their ability to control drug spend. The question is: How aggressive can they get? This year's updates signal potential difficulties in expanding drug exclusions into sensitive drug classes, as some "bold" moves in previous years have been reversed.

CONCLUSION

For providers and health systems, practice patterns impacted by last year's exclusion lists may be disrupted again, specifically as they pertain to those potential sensitive areas and where drug status has flip-flopped over the past couple of years. With a greater push toward value-based care, the impact of these changes on overall outcomes—both clinical and financial—needs to be assessed and used to inform future exclusion decisions. Otherwise, pricing and rebate contracting between PBMs and manufacturers will likely continue to be the driver for these decisions. ◆