DRUG CHANNELS
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Navigating Market Access Challenges in Life Sciences Commercialization

Today's guest post comes from Bill Dupere, SVP of Product Development & Partnerships at Mercalis.

Bill discusses specialty therapy access barriers, including payer utilization management techniques and "no coverage" policies. Contact Mercalis to learn about their Patient Support Services.

Read on for Bill's insights.


Bill Dupere

Navigating Market Access Challenges in Life Sciences Commercialization

By Bill Dupere, SVP, Product Development & Partnerships, Mercalis

Readers of *Drug Channels* understand the commercialization of life sciences products is complex and correlated to each product's profile. Common product archetypes range from cash pay for generics to highly personalized medicine via cell and gene therapies. Consulting frameworks exist to identify and prioritize the workflows for the healthcare provider, prescription, and patient access journey, respectively.

Routine access considerations include diagnostic workup, treatment decision, insurance eligibility, coverage determination, and clinical justification—with or without referring patients for enrollment into brand.com support services. Other access considerations encompass payer coverage and reimbursement policies, payer contracts, discounts, rebates, and trade channel distribution agreements.

Most new life sciences assets target specific biological, cellular, molecular, or other pathways that alter disease progression. Improved quality of life, increased life expectancy, or a medical cure are legitimate outcomes for many diseases. Downstream from diagnostic workup, proper patient selection, and defense of clinical appropriateness, questions remain as to whether patients can afford therapy. As such, Mercalis thrives as a life sciences commercialization partner that specializes in market access solutions.

At a macroeconomic level, payer utilization management (UM) techniques are mature, sophisticated, and often create patient access barriers to specialty therapeutics. Common UM techniques include mail order pharmacy, preferred provider networks, in-house (or outsourced) Pharmacy & Therapeutics committees, active formulary management, and monopsony purchase power (which now includes private-label generics and biosimilars). Formal UM has been effective at reducing drug costs now that both Medicare Part D and Medicaid managed care plans adopt similar UM techniques. UM advocates position these tactics as reasonable and necessary to control drug costs.

But have mature UM techniques gone too far? It is unfortunate that market access specialists must now spend time identifying the plans, or contracted intermediates, that purposefully exploit loopholes in the Affordable Care Act, patient assistance program eligibility criteria, and copay assistance programs. Life sciences commercialization planning should expect a significant percentage of health plans to deploy drug benefit designs that categorize specialty therapeutics as nonessential healthcare benefits.

The ensuing "no coverage" policies are written with vague language that allows third-party intermediaries to target patient enrollment into patient assistance (free drug) programs, or not recognize (i.e., intercept) copay dollars towards a patient's deductible. Large insurers are on public record advocating that these policies help to reduce drug costs. However, payer assault on targeting patient support services does adversely affect access to care. This was the primary catalyst for the federal lawsuit led by a coalition of individual patients and HIV/Diabetes patient advocacy groups to sue Health and Human Services (HHS).

In this case, a judge overturned the 2021 Centers for Medicare & Medicaid Services (CMS) provision that allowed insurers to use copay accumulator tactics. Even though the Biden administration has decided not to appeal, it filed motions indicating there will be no enforcement action against healthcare insurers who continue to use copay accumulators. These policies persist regardless of state legislative momentum nationwide to disallow copay accumulators. Of course, copay maximizers are not addressed in most state legislative initiatives.

To recap, there is a societal collision of market dynamics regarding the economics of drug contracting and pricing, including the growing catalog of FDA-approved specialty therapeutics, sophisticated PBM UM techniques, a lack of transparency, and a willingness to exploit loopholes and/or blur ethical boundaries for financial gain. Market access specialists have witnessed firsthand how public understanding may be ill-informed, positioning biopharma drug pricing as the culprit.

Price transparency is real. Payors will not be able to hide much longer due to changing statutory requirements and public pressure. The market is accelerating towards making the cost of care accessible and understandable for patients. Whereas myriad barriers to access have always been evident, there is more pressure to actively manage each milestone in the patient access journey.

Eligibility determination for patient support services is much more specific relative to the recent past. Efficiency gained through eServices and other technologies is a prerequisite. And initial AI pilots for patient support services use cases suggest AI can be done in a compliant manner, particularly when the reference source is limited to a predefined validated dataset.

Mercalis is fulfilling its mission, providing end-to-end life sciences commercialization services with a particular focus on market access solutions. Mercalis, as a life sciences commercialization partner, can provide tailored market access solutions that identify and mitigate barriers to access at every milestone throughout the patient journey. To learn more about Mercalis Patient Support Services, please contact us at sales@mercalis.com.
