Biologics and Biosimilars: Prescription Pathway and Points of Influence

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For industry, the path of the biologic prescription, once written, may see a number of influence points that affect market share, marketing plans, patient support programs (PSPs) and prescribers. And, most importantly, your patient. While this is not a new phenomenon, in the world of biologics and biosimilars there are unique reasons for evolving influence. Given the mix of government guidance, landscape policies, new terminology and old concepts, and practices based on our long history with traditional medicines, we have some distance to cover.

What's in a name?

When a biologic medication is ordered using the chemical name rather than the brand name, clarification of the order by the prescriber is required, since they are not interchangeable at the pharmacy. Studies show that while physician knowledge is improving when it comes to biosimilars, the knowledge gap is still significant. As a result, external input at the point of clarification from pharmacists, payers and organizations offering opinions and recommendations can influence final product selection.

Health Canada has decided that both the brand name and the non-proprietary name should be used throughout the medication use process so that biologics that share the same non-proprietary name can be distinguished by their unique brand names. Ultimately, how the prescription is written may not matter so much if reimbursement is the obstacle.

What about the PSP?

Let's assume for a moment that the prescription, whether prescribed by reference brand or chemical name, is only covered for the biosimilar option. To change a prescription to the covered biosimilar will require physician authorization, assuming the patient opts not to pay out of pocket for the innovator. If that original prescription had resulted in the patient's enrollment in the associated PSP, would it be reasonable to expect that a PSP for one drug would work to facilitate any part of changing the prescription to its biosimilar, in order to facilitate reimbursement? Ideally, there would be a single point person and the straightest pathway possible for the patient. We will need procedures for managing such circumstances in a patient-centric manner.

What about multiple biosimilars for one molecule?

As multiple biosimilars for one molecule enter the market, it will become a challenge for pharmacies to stock all the options and we may see a pharmacy select one "preferred" biosimilar in such cases. Is the selection likely to be influenced by the identity of the biosimilar's manufacturer, i.e. whether it is an innovator company or a generic company?

Discussion

Health Canada's guidance on biosimilars is quite clear and there are many influential landscape participants beyond Health Canada, almost all with strong biases based on their frame of reference. These include physicians, payers, patients, pharmacists, shareholders and pharmaceutical companies. The participants also have many competing interests, both clinical and economic. The balance between care and commerce can be tricky.

We want it all. We want the innovation and certainly patients need the innovation. We also want better value, however that might be defined. With collaboration and the patient at the starting point of all decisions, we probably can have it all.

For the health care professional, it can be challenging to determine the right decision for the individual patient, especially as parameters may vary by patient type, by molecule, by indication and perhaps by manufacturer. One size, one policy may not fit all. Who or what should be most influential in such decision-making? Furthermore, whoever or whatever that is, how do we ensure that the patient is central in the process rather than the stakeholders' vested interests across the entire continuum of participants? It will be increasingly important to intimately understand the prescription pathway, the points of influence and the patient's journey in order to truly appreciate the implications for your product.

Regardless of how the biosimilar pathway evolves, some fundamentals will be challenged in new ways. As innovators of biologics work to defend their market share, the landscape works just as hard to access savings from biosimilars. Action. Reaction. Both efforts are justifiable, and each may extend to new limits in the short term. Is it time for contingency planning?

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