BIOLOGICS, BIOSIMILARS AND YOUR BENEFITS

BIOLOGIC DRUGS HAVE DRAMATICALLY IMPROVED THE QUALITY OF LIFE FOR PATIENTS WITH RHEUMATOID ARTHRITIS, CROHN'S DISEASE AND OTHER CHRONIC ILLNESSES.

But given their high cost, there is a growing interest among plan sponsors to switch to biosimilars. There are risks to switching, however, particularly with regard to non-medical switching. The recent Benefits Canada Webinar "Biologics, Biosimilars and Your Benefits" examined the clinical, legal and patient issues for plan sponsors related to implementing plans that encourage switching from a biologic to a biosimilar.

EXAMINING THE EVIDENCE

Doctors frequently switch patients' medication if they no longer respond to the treatment or experience adverse events, but with non-medical switching, a stable patient's therapy is changed solely to lower drug plan costs. Although there is growing number of studies on biosimilar switching, Doctor Arthur Lau, assistant professor in the division of rheumatology at McMaster University, cautions that "we are still very early on with what we know about the safety and effectiveness of non-medical switching."

Lau reviewed several studies on biosimilar switching and expressed misgivings about some of their conclusions. One recent systematic review of studies, for example, found that switching patients from an originator biologic to a biosimilar was not inherently dangerous. Lau disagrees, citing concerns about the study's limitations. "The studies selected were for a wide variety of conditions, which did not allow a direct apples-to-apples comparison. In addition, many of the studies included were low in quality and small in size."

Lau also examined two frequently referenced European biosimilar switching studies. While the NORSWITCH study included a large number of patients, Lau feels it had too few patients for each disease state to make a definitive conclusion about the impact of switching.

Mina Mawani, President and CEO of Crohn's and Colitis Canada, concurs. "The NORSWITCH study did not have enough IBD patients and Crohn's disease patients," she notes, adding that many of those who switched reported more flare-ups than those who did not.

The DANBIO registry monitored a large cohort of patients who were mandated to switch to a biosimilar. Although there was no significant change in disease activity after switching, Lau notes that 15% of patients stopped the biosimilar after a year, a higher-than-normal quit rate.

Lau concludes: "There are limited studies on biosimilar switching and this field of research is still in its infancy. The studies we've seen so far leave some unanswered questions and we need more research to help us make a decision on whether non-medical switching is appropriate or not."

LEGAL LIABILITY GROWING

Non-medical switching also increases the potential for legal challenges, cautions Tara Anstey, Principal in the Halifax office of Mercer (Canada) Limited. "If your plan documentation doesn't clearly support your claim practices, including those that may drive patient switches, courts will likely find against you."

Anstey encourages plan sponsors to take ownership of their plan documents, especially for administrative services only (ASO) plans, where the plan sponsor has a fiduciary responsibility to oversee the claims payer. For insured plans, the carrier is generally responsible for litigation defense under the insurance contract, whereas ASO plan sponsors have historically borne the full liability for legal challenges. "Plan sponsors may be able to mitigate their exposure to legal risk and transfer it to the provider," Anstey notes. "We are seeing a growth in ASO plan sponsors asking claims payers to stand behind their products and assume the liability for defending plan language just as they would for an insured plan."

This is an emerging area of law, however, with little case law to provide clarity on how a court might view challenges to claims limitations. As a best practice, Anstey recommends that plan sponsors become actively engaged in understanding the drug plan philosophy and the criteria that ultimately guide what is covered. "They should take responsibility for their documentation to demonstrate that their provider is managed and overseen," she explains.

"Patient switching is a new frontier for plan management and it's important to understand your legal risks," Anstey emphasizes. "You need to understand how the provider is managing claims, including exception processes, ensure that plan documentation supports these practices and also understand whether the provider will defend legal challenges."

IN THE PATIENT'S SHOES

For many patients, biologics are highly effective at putting their disease in remission, yet they live with anxiety of their medication failing and their symptoms returning. Mawani points out that those who are stable on their biologic treatment do not want to switch to a biosimilar without first consulting their physician.

There's also the risk of the "nocebo effect" to consider. "When patients are aware that a change of treatment is done for non-medical reasons," explains Mawani, "they may fear the change in treatment isn't the optimal health outcome choice. This fear can influence the outcome of disease."

Canada is unique in that switching from a biologic to its biosimilar typically means switching infusion clinics. Biologic infusions are delivered at private clinics through a pharmaceutical manufacturer's third-party patient support program whereas patients in many other countries can continue at the same hospital clinic with the same medical team and simply receive a different drug.

Whatever the reason, if a patient loses treatment effectiveness they may experience a flare, could have to be hospitalized, and are likely to miss work or school until they can stabilize their symptoms once again.

Mawani concludes by noting that the Best Medicines Coalition, a national alliance of over 25 patient organizations, has broad consensus that patient/doctor medication choice is paramount, which includes not being required to take a different drug for non-medical reasons.