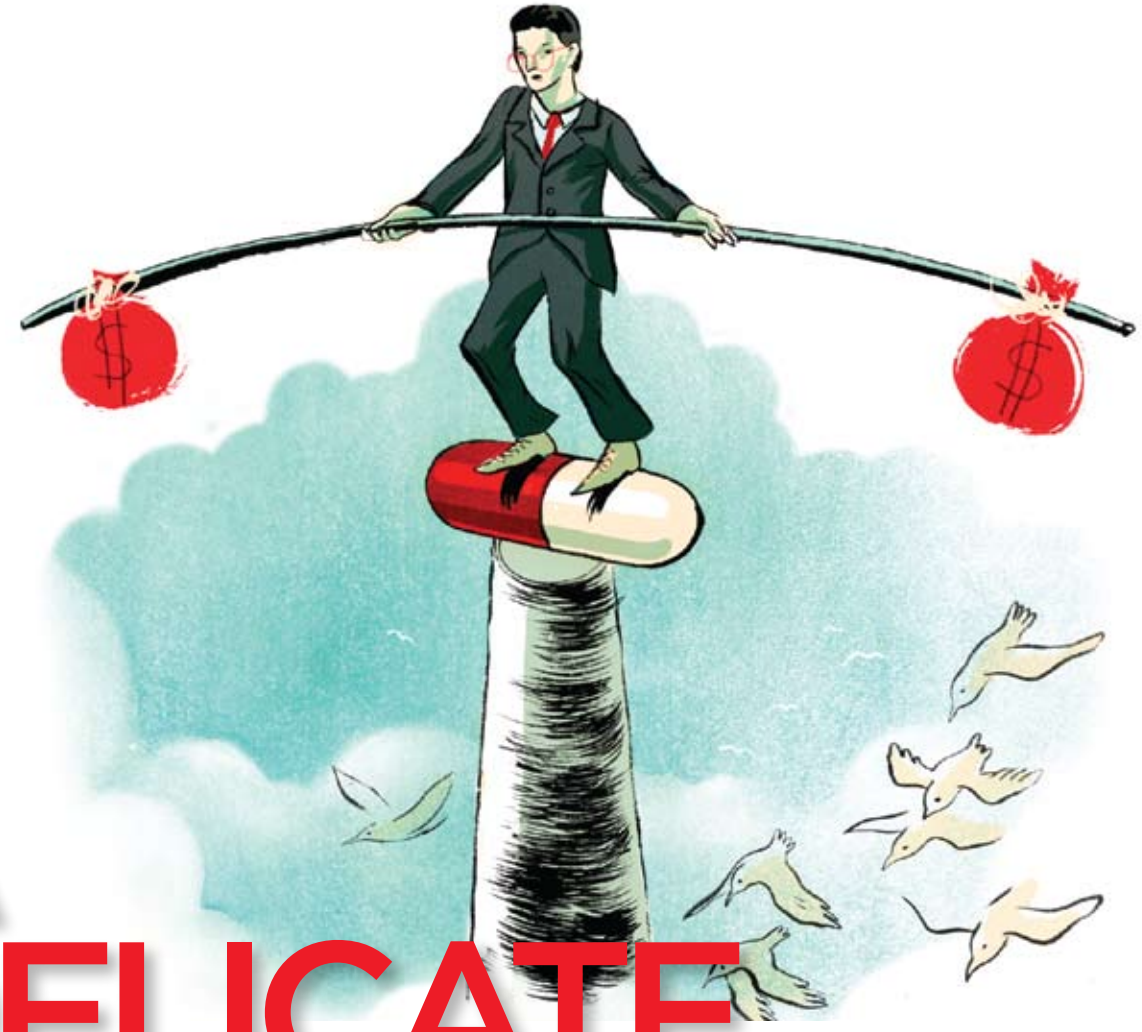

A DELICATE BALANCE

How can plan sponsors weigh the needs of their plan members with the high costs of biologic drugs?

BY SUZANNE LEPAGE

Although David showed early symptoms in his late teens, he was only diagnosed with rheumatoid arthritis (RA) once he was well established in his career. His symptoms progressed to the point where it became difficult for him to manage the day-to-day requirements of his role. Although he suffered, his commitment to show up at work every day prevented him from going on disability.

Fortunately for David, in the late '90s—after many inadequate treatments—his rheumatologist found a combination of medications that worked, including the biologic drug Enbrel. These treatments not only provided him with relief but practically put his condition into remission. The year following these treatments, David says, was his most productive and profitable, and he was promoted to a senior operations position. For 10 years, David West has managed and grown the Toronto operations of Mercer Human Resource Consulting, thanks to a biologic drug.

West brings a unique perspective to the challenges and benefits of managing

BYRON EGGENSCHWILER

biologic drugs in group plans. He understands the challenges of plan sponsors in managing their drug plans and the impact that long-term disability (LTD) costs can have on the bottom line. To Mercer, West's annual treatment cost of $21,500 was not only an investment in his health and productivity but also a way to avoid significant LTD costs. West provided strong leadership and growth to the organization once he was able to manage his symptoms.

Impact on Private Drug Plans

Biologic drug price tags may be higher than those of traditional drugs, but they treat a much smaller patient pool. According to ESI Canada's 2008 *Drug Trend Report,* specialty or biologic medications represent 14.7% of drug spend but less than 1% of all claims. What most concerns private drug plan managers is the annual growth rate of specialty drug spend: 17% compared with 3% for all other drugs. Biologics offer tremendous clinical value, but they also represent more than 50% of the drugs in the pipeline.

ESI Canada examined claimants with more than $5,000 in annual claims and, as expected, many were using specialty or biologic drugs. What you might not expect, however, is that many of the high-cost claimants were taking these medications for chronic conditions such as diabetes, high blood pressure and high cholesterol. Many of the conditions treated by biologic drugs are not preventable—for example, RA, Crohn's disease, cancer and multiple sclerosis. However, diabetes, high blood pressure and high cholesterol are near the top of the high-cost claimant list, affect a large patient population and could be addressed or prevented through modifiable risk factors and healthy lifestyle choices.

Because of the significant differences in size and molecular makeup of biologic drugs, they are not very stable in the gastrointestinal system and are best suited to intravenous (IV) administration. In Canada, IV drugs are often delivered in a hospital. This raises a whole new complexity for private plans whose group contracts exclude drugs administered in a hospital.

Many insurers consider these "insured hospital services" under the *Canada Health Act* and believe that the hospital should fund them, meaning the private plan will decline the claim if the drug is infused in a hospital. Even more confusing, some private plans pay for treatment if the drug is delivered in one of a growing number of private infusion clinics in Canada. Yet there are concerns about moving a patient outside of the hospital setting and traditional care stream for treatment, such as coordinating patient charts, medical records and lab work.

Because of the complexities of private drug plans, patients are often bewildered as they try to understand their coverage for biologics. As a result, a variety of different patient assistance program options have evolved to help patients determine what coverage is available to them. These programs may be funded by hospitals, drug companies, not-for-profit groups or public health plans, but they all serve the same purpose: to provide skilled staff to assist a patient in navigating his or her available coverage. These programs advocate on behalf of the patient for public, private, compassionate and even international medication access. They are highly valued by, and bring comfort to, patients who are distracted by their disease and its effects on their health.

The Plan Sponsor's Response

In Mercer's case, its clients tend to be larger plan sponsors that are more concerned about total compensation costs than the specific cost drivers of their drug plans. Rather than tinkering with drug coverage, many plan sponsors are moving to employee-paid disability benefits to manage costs and allow members to take advantage of non-taxable benefits. Plan sponsors are also ensuring that they have pooling protection for their drug plans to protect against the impact of catastrophic drug claims.

West feels that there are opportunities to better understand the correlation between drug costs and disability costs, and that the insurance industry has a wealth of data that could be studied. He also recommends that we continue to explore private and public partnerships for pooling and patient protection from large out-of-pocket costs.

Rob Crofts, vice-president, group benefit solutions, with Corporate Benefit Analysts, deals primarily with mid-size clients that feel that the drug benefit is one of their most important employee benefits. They believe that biologic drugs are breakthroughs in treating serious medical conditions; however, they are also very concerned about the potential impact on costs.

Many clients find drug plan management complicated and difficult to communicate to employees. They rely on their advisor, insurer and pharmacy benefit manager (PBM) to ensure that the plan is effectively managed—for example, using prior authorization to ensure that members meet the clinical guidelines for biologic drugs. Clients also rely heavily on pooling arrangements to protect their plan experience and rates from the impact of large biologic drug claims. What they are finding, though, is that in order to keep pooling charges affordable, insurers are more frequently increasing the claims threshold levels, which can erode the level of protection over time.

Vic Medland is president of group insurance services at the Ontario Teachers Insurance Plan (OTIP), which manages benefits for more than 112,000 members within the Ontario education sector. Biologic drugs to treat RA are the top drugs in the plan, and OTIP views prior authorization as an effective tool to ensure that the right member gets the right drug at the right time.

Medland believes that covering biologic treatments for catastrophic conditions is an important component of what insurance plans are designed for, but the issue of paying only for infused drugs in a private clinic is an area of frustration. In one situation, this meant that a plan member who was in severe pain had to drive to a private clinic 45 minutes away, versus receiving an infusion in the community hospital. Out of compassion for the member, OTIP decided to pay for the infusion in the hospital, since it would have paid if the plan member had travelled to the private clinic. However, OTIP would really like to see this issue resolved rather than having plan members being caught in the middle.

The Facts on Subsequent Entry Biologics

- Subsequent entry biologics (SEBs) are biologic drugs that enter the market subsequent to, and similar to, innovator products authorized for sale in Canada.
- SEBs are not "generic biologics"—many characteristics associated with the authorization process and marketed use for generic pharmaceutical drugs do not apply to them.
- Authorization of a SEB in Canada is not a declaration of pharmaceutical and/or therapeutic equivalence or an indication that the product may be automatically substituted with its reference biologic product.
- The principles and procedures for the authorization of generic pharmaceutical drugs are unacceptable for biologic drugs. Along with a full complement of quality information, some original non-clinical and clinical data are required to support a SEB application.
- This will impact the cost of developing the SEB. As a result, SEBs likely won't generate the same savings associated with the introduction of traditional generic drugs.

ALTHOUGH PLAN SPONSORS MAY NOT BE ABLE TO AVOID BIOLOGIC DRUG CLAIMS, THEY CAN IMPLEMENT PROGRAMS TO BETTER MANAGE THEM.

According to Lisa Callaghan, assistant vice-president, product development, group benefits, with Sun Life Financial, the way plan sponsors view biologic drugs is based on a number of factors including their funding arrangement, which impacts how plan risk is managed. In administrative services only (ASO) plans, plan sponsors are responsible for all of the financial risk upfront. Given that ASO plans tend to be adopted by larger employers, they may be in a better position to absorb an isolated catastrophic biologic drug claim than smaller organizations. Smaller clients often adopt insured drug plans, which provide a level of protection against the immediate financial impact of a single catastrophic claim. However, premiums will likely reflect increasing drug costs over time.

While biologics have the potential to offer significant clinical value, Sun Life Financial, like many others, is looking cautiously at the potential impact of biologics on drug plans. "The funding of biologics through private plans is a complex issue that lacks a simple answer," Callaghan adds. "The potential for improved health and quality of life must be balanced against the impact of substantially higher costs on the sustainability of private plans."

Tools for Drug Plan Management

Although plan sponsors may not be able to avoid biologic drug claims, they can implement programs to better manage them. The first step is to ensure that biologic therapies are being used appropriately.

While patients on biologics are typically under the care of a specialist who is well trained to treat the related conditions, drug plans can still implement criteria to ensure that patients are receiving evidence-based treatment (using drugs as approved by Health Canada based on established clinical guidelines). This may require forms to be completed by a physician and reviewed by the insurer or PBM. On the surface, this may seem like an administrative burden; however, there may be an opportunity for some savings by ensuring that the right patients are getting access to medications.

Clients can elect managed or tiered formularies as a means of helping to control the impact of potential catastrophic claims. Plan sponsors recognize that by covering only certain drugs through the formulary, they are potentially affecting the member's ability and desire to fill a physician's prescription that is not covered under the plan. While some plan sponsors elect to implement prior authorization for certain drugs, they must evaluate the potential cost savings versus the impact of the strategy on plan administration and employee relations. It is still the norm for plan sponsors to choose open formularies; therefore, they often rely on other drug plan management tools to manage costs without limiting access to medications.

Green Shield Canada has taken a more aggressive approach to managing biologic drugs. Sal Cimino, manager, pharmacy and professional services, and his team did a thorough review of the biologic drug class in 2008 and moved to a tiered reimbursement model, in which certain biologic therapies must be used as first-line therapy based on their cost and effectiveness. Every biologic claim is subject to prior authorization to ensure that the plan member uses biologic medications in the recommended sequence. This model ensures that the most cost-effective medications are tried first; then, if the patient is intolerant or fails on the preferred therapy, he or she can move to alternative medications. Green Shield Canada hopes to conduct a study of this plan design in 2010 to determine the savings and impact on plan sponsors.

In the U.S., where plan sponsors are also responsible for the healthcare costs of their plan members, there is significant growth in the area of therapy management. The U.S. PBM Medco and its subsidiary, Accredo (a specialty pharmacy), offer programs to plan sponsors to support members who are receiving specialty or biologic medications. Because of the complexities in administration, dosing and follow-up, these plan members require significantly more service and support than those taking traditional medications.

A team of specialized pharmacists and nurses is trained in the medications used to treat specific conditions, providing plan members with specialized support, training and mentoring beyond retail dispensing of medications. Through follow-up calls and monitoring, these professionals ensure that plan members are using the medications effectively and completing tests as required, encouraging adherence to optimize the plan sponsor's investment in the drug and the plan member's improved health.

Although these programs are emerging in Canada, there has been very little uptake in this area by Canadian private drug plan sponsors. But as their investment in specialty and biologic drugs grows, they may want to consider these programs to ensure that their investment is being managed effectively.

Regardless of the type of plan sponsor or drug plan, everyone agrees that biologic drugs have had—and will continue to have—a significant impact on private drug plans. Not only have they improved the health of many plan members, but they require plan sponsors to take a closer look at their drug plans and carefully consider what kind of coverage and protection they want to provide. **BC**

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