ON THE RADAR

The costs of biologics are looming large. Is your drug plan ready?

By Sal Cimino

From the state of the economy to the implementation of drug reform legislation and prolific genericization of branded products, there has been much speculation about the impact that biologic drugs will have on private plans. Less than five years ago, most of this discussion took place in the future tense. Long development times in the pipeline—combined with a heavy degree of media attention on the "futuristic" nature of newer, more complex agents—instilled in many plan sponsors a lingering feeling that biologics were just a distant blip on the radar.

Many plans now realize that biologics are growing significantly as a percentage of the total drug spend in Canada for both private and public payers. While it is difficult to get a good picture of biologic trends in Canada, we can look to the U.S. for some context. According to a 2011 Thomson Reuters–Newport report, sales of the top 12 biologics in the U.S. reached roughly $30 billion in 2010. The issue for plan sponsors and employers today is managing coverage of these agents, knowing that many are both effective and pricey. To do that with authority, plan sponsors need to understand what biologics are, as well as what to expect in terms of their use and cost.

History Lesson

The use of biologics is not a recent development. Insulin (which has been used in Canada to control diabetes since the early 20th century) and vaccines (first developed in the late 19th century) are part of this group, as are drugs derived from bacteria and micro-organisms (excluding antibiotics) or developed through specialized methodologies such as recombinant DNA procedures. Health Canada also considers blood and blood products, as well as other agents that span a number of therapeutic categories, as biological products.

One of the key differences between traditional pharmaceutical medications and biologics lies in how each is manufactured. The former are chemically synthesized in a process that is relatively easily replicated—think of these as recipe-based products. The latter are derived from living cells, tissue or micro-organisms using much more complex, highly controlled manufacturing processes that are unique to each drug. They are more expensive to research, manufacture, store and deliver than pharmaceuticals—and, as a result, they can cost the plan sponsor much more.

One class of biologics has come to dominate the field of drug benefits. This class—called the immunomodulators and antineoplastics—includes a number of products used to treat severe rheumatoid arthritis (RA), juvenile RA, Crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis, ankylosing spondylitis and cancer. These drugs first appeared in Canada in 2001 with the introduction of Enbrel for the treatment of RA. The number of drugs on the market and the scope of indications for use have grown significantly over the past 10 years.

While the pace of approvals for new biologics in Canada and the U.S. has slowed somewhat in recent years, the number of indications for existing agents has increased. As biotechnology-driven product development becomes an attractive focus for research-based pharmaceutical companies, plan sponsors can expect to see more products and higher sales in the near future.

The Thomson Reuters–Newport report also notes that fewer than 1,200 clinical trials for biologics were under way between 2000 and 2005. Over the next five years, that number swelled to nearly 6,000 trials. In 2009, the U.S. think tank EvaluatePharma suggested that in 2014, six of the top 10 drugs will be biologics.

Also under the "future-is-now" theme is the concept of therapeutic vaccines (used to treat a disease instead of preventing it), some of which are tailor-made for patients using their own DNA. In *Emerging Cancer Vaccines: Forecasts, Developments and Pipeline Analysis,* 4th Edition, healthcare market research publisher Kalorama Information in the U.S. estimates that the cancer vaccine market alone could be worth US$7.7 billion by 2015. The new therapeutic vaccine Provenge (marketed in the U.S. for treating prostate cancer) is thought to add approximately four more months of overall survival; however, it costs almost $100,000 per patient.

The Green Shield Canada 2010 *Drug Trends Study,* conducted in partnership with Brogan Inc., analyzed more than 56 million drug claims across Green Shield's entire client base from 2005 to 2010 to assess trends in drug spending and utilization. The data in this survey represent the entire amounts paid out for each claim, including what Green Shield pays on behalf of the plan sponsor and what the plan member pays out of pocket. Following are some of the study findings as they relate to biologics.

- Biologics grew from 8.3% of the total share of drug spending in 2005/06 to 11.3% in 2009/10. This increase was led by immunomodulators (biologics such as Humira, Remicade and Enbrel) and antineoplastics.
- The total spend on biologics increased from 2005/06 to 2009/10, with an average compounded annual growth of 12.1%. That growth rate is now slowing due to a plateau in new indications and agents within the biologics class (immunomodulators and antineoplastics) that drives most of the costs for this category.
- The most expensive 5% of claimants are driving more than 40% of plan costs. Those numbers may not be surprising, but what's driving that spending is enlightening: almost 50% of those costs are directly attributable to biologics.
- Digging deeper into this finding, analysts found that the 35- to 44-year-old age group had the highest annual growth in costs, at 3.4%—again, due to biologics use.

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Costs Under the Microscope

As biologics ramp up their dominance of private payers' drug spend, what can plan sponsors do to balance the clinical use of biologics with cost containment?

Understand what's going on in your plan – Robust data are the cornerstone to setting a flexible policy that captures maximum savings today while positioning you to make efficient course corrections when they're required. Even a small percentage point change in costs with these pricey drugs can make a significant dent in your plan's drug spend.

Cover the most cost-effective product – Any major price differentials within therapeutic classes of biologics are due primarily to price competition. All plans should default to covering the most cost-effective agent within a class first, allowing a plan member to move on to other agents in the class only when he or she experiences an undesired response to the first drug.

Typically, when we think of lower-cost agents, we think of generic drugs. The correct terminology is *subsequent entry biologics* (SEBs), and they will offer fewer potential savings than traditional generic drugs as compared to brand name drugs.

Since biologics are susceptible to therapeutic differences caused by even slight changes in manufacturing processes—and since those processes themselves are protected intellectual properties—manufacturers of SEBs essentially have to invent their own processes to "imitate" the original drug. This will keep costs high. Although savings on SEBs may be only in the 15% to 20% range compared with innovator products, they are still worth considering as mandatory substitutions as they become available. Setting a plan policy that automatically reaps potential savings requires sound research and analysis, as well as a high degree of engagement with consultants who can reliably assess relative efficacy and determine cost-effectiveness.

Communicate your policy – Plan members often view drug benefits as a simple customer value proposition: a yes or no on a drug's coverage tells them whether or not their drug plan is a worthwhile benefit. Clearly communicating your plan's policy on biologics so that members can understand why certain drugs are covered can help reinforce the value of a benefits package. It can also help to ensure that a drug covered under the plan will be prescribed at the outset, which removes the need for claim denials at the pharmacy level.

Biologic drugs represent a new vista of treatment options for a wide range of diseases. Many of them are effective in getting people back to work—and keeping them there. The time has come to make biologics an active part of the conversation on drug plan philosophy, design and policy. Applying sound logic and careful measurement to your biologics policy can help to ensure that plan members get the right drug at the right time—and at the best possible price.

Sal Cimino is director, pharmacy services, with Green Shield Canada. sal.cimino@greenshield.ca