Benefits CANADA

Preparing for the drug pipeline

Mike Sullivan | May 11, 2012

It has been easy since the spring of 2010 for plan sponsors and advisors to be preoccupied with generic drug pricing reform. It seems that every month, another province is stepping up to the microphone to share its new vision for saving money or coming back with Version 2.0 of its original pricing reforms. It's strange that, in all of this, there has been very little attention placed on the 70% to 75% of private plan spending that is still represented by spending on brand name products. It's even more surprising that there is less focus on the pipeline of innovation that awaits the marketplace.

According to Express Scripts, the largest pharmacy benefit manager (PBM) in the U.S., in 2011, the cost of traditional pharmaceutical products south of the border increased by just over 0% from the year before. At the same time, specialty drug (i.e., expensive, targeted biologic and non-biologic therapies) spending increased by 17% during the same period. Express Scripts predicts spending on traditional drugs to be negative in 2012 (thanks to generic Lipitor and Plavix), but it also predicts the specialty side of the business to grow by more than 20%. This is relevant to us in Canada because we typically lag behind the U.S. Federal Drug Administration (FDA) in approving specialty therapies. This continued growth in specialty utilization and spending south of the border will foreshadow what we can expect to see here.

It is always interesting to read pundits predicting the pending demise of major industries such as the automotive industry in North America and, more recently, the pharmaceutical industry. Granted, these are not the greatest of times for brand pharma, but we shouldn't be too quick to discount what's coming down the pipeline. Take the following as evidence that the pharmaceutical industry hasn't exactly thrown in the towel, and that there are a number of innovations on the way.

- According to OptumRx, another American PBM, the pipeline of drugs now sits at 1,150 products. While that number is lower than what was seen between 2004 and 2011, it is materially higher than the period from 1998 to 2003 when the blockbuster drug business model was in full swing.
- Approximately 350 of these products are in Phase 3 or later in their development cycle.
- The focus now has swung squarely on specialty products, with 30% of the pipeline comprising cancer drugs. In 2011, the FDA approved three times more specialty products than it did in 2009.

The innovations are not uniquely specialty-driven. One of the most telling statistics about the drug pipeline is that most manufacturers have completely shifted their focus away from areas such as cardiovascular therapies. Do we really need another drug for blood pressure or cholesterol, given the wonderful innovations we have seen in these areas over the last 20

years? It looks as if the industry agrees, given that there are more diabetes therapies in the pipeline than cardiovascular therapies. That has never happened, or even come close to happening, in the past.

Innovations to watch for

Below are some agents that are worth watching, and the list is proof that plans that are not well managed will struggle with unexpected cost increases. Some of these products may not get to market, some may not meet with tremendous commercial success, but keep in mind that this is only a sample of what is coming. It's great news if you have a serious illness, but not so great news if your plan isn't properly designed and able to maximize the value in traditional areas of plan spending in order to afford what is coming.

Immunology

This has been an area dominated by injectable products, and it is the leading area of specialty drug spending for a vast majority of Canadian plan sponsors. Remicade, Enbrel, Humira and Simponi have become well-known products to treat rheumatoid arthritis (RA), Crohn's disease, psoriasis and psoriatic arthritis (PsA). Here's what is in the pipeline:

Tofactinib – oral therapy to treat RA and psoriasis, due for U.S. approval in 2012;
Apremilast – oral therapy to treat PsA and psoriasis, due for U.S. approval in 2013; and
Fostamatinib – oral therapy to treat RA, due for U.S. approval in 2013.

Multiple Sclerosis

Multiple sclerosis (MS) is another category dominated by injectable products saw the first oral agent (Gilenya) introduced last year in Canada. MS is often the second- or third-most expensive specialty class for a majority of Canadian plans. Here's what's coming:

Teriflunomide – oral therapy, due for U.S. approval in 2012;
Dimethyl Fumarate – oral therapy, due for U.S. approval in 2013; and
Masitinib – oral therapy, due in 2014.

Oncology

Canadian plan sponsors have been very lucky to date. The vast majority of oncology spending continues to be picked up by provincial cancer care programs, but with a growing incidence of cancer, a vast pipe of expensive innovations, and provinces such as Ontario that won't have the money to keep covering every new innovation, this is where we see private plans facing a significant increase in spending. The other issue for private plans is that some of these new, targeted oral therapies may not be covered as first-line agents by provincial plans; therefore, the cost may fall to plan sponsors.

Zelboraf – oral therapy for malignant melanoma, approved by the FDA in 2012;
Xalkori – oral therapy for non-small cell lung cancer, approved by the FDA in 2012;
Inlyta – oral therapy for kidney cancer, approved by the FDA in 2012;
Erivedge – oral therapy for skin cancer, approved by the FDA in 2012;

Taltorvic – oral therapy for sarcoma, approval expected in 2012;
Bosutinib – oral therapy for leukemia, approval expected in 2012;

Actimid – oral therapy for multiple myeloma, approval expected in 2013;
Cabozantinoib – oral therapy for thyroid cancer, approval expected in 2013;
Enzalutamide – oral therapy for prostate cancer, approval expected in 2013; and
Regorafenib – oral therapy for colorectal cancer, approval expected in 2103.

We are fortunate to live in an era where blockbuster generic products are making traditional categories much more affordable, and to live in a time of great innovation on the brand side. There is a significant opportunity for plan sponsors to extract even more value out of every dollar they invest in the health of plan members, but that won't happen without *active* plan management.

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