WILLIAMS LEAL & VITO INC

April 2016

Williams Leal & Vito has prepared the following report on future Drug therapies and the cost effect on they will have on future Employer healthcare premium rates.

Drug Trends

Specialty Drugs approvals are rising above traditional drug approvals. Approximately 40% of all drugs being reviewed by Health Canada are Specialty drugs. The FDA's estimates greater than 60% of all drugs being reviewed for approval are for NEW specialty drugs. Specialty drugs are not only biologics anymore, the drug industry is seeing a shift of specialty drugs for lower level chronic conditions, like high cholesterol, asthma, heart failure and migraines. Traditionally specialty drugs were developed to treat complex chronic conditions like Multiple-Sclerosis, Rheumatoid arthritis and Hepatitis C.

What constitutes a "specialty drug"

- Special manufacturing techniques (use of bacteria and live viruses)
- Special distribution (monitoring and refrigeration)
- Special administration (infusion or subcutaneous injection)
- Treat a small percentage of the population
- Typical annual cost $10,000 or greater
- Generally prescribed by a specialty physician

A large proportion of specialty drugs are "*biologics*". These are considered innovator drugs developed under patent. These drugs are made with living cells opposed to chemically constructed. Two most commonly known biologics are Remicade, which treats Crohn's disease, Colitis and Rheumatoid arthritis costing $20,000 - $95,000 per year and Sovaldi, which treats Hepatitis C costing about $60,000 per year.

A new wave of specialty drugs are the *Subsequent Entry Biologics (SEB) or Biosimilars*. These are similar drugs but not identical that enter the market once the original biologic drug's patent expires. SEBs generally cost less; Inflectra for Rheumatoid arthritis costs approximately $15,000 - $30-000, quite a bit less than Remicade. Drug companies must meet standards for interchangeability, these are still in development in both Canada and the United States. Biosimilars are available at a lower cost than their counter part.

Biosimilars Approved in Canada

Brand Reference	Biosimilar	Biosimilar Approval	Discount
Genotropin	Omnitrope	04/20/2009	25.54%
Remicade	Inflectra	01/15/2014	46.84%
Lantus	Basaglar	09/01/2015	15.00%
Neupogen	Grastofil	12/07/2015	16.67%

*SEBs are not to be confused with "generic" drugs. Generic drugs are identical at the medical ingredient level.

New *oral tablet specialty drugs*, mainly to treat cancer make up about 30% of specialty drugs in development today. This will shift the drug cost to private sector because the drug can be taken at home instead of a hospital.

Rare disease drugs, also known as orphan drugs, target diseases that only affect a very small part of the population. Canada's Orphan Drug Regulatory Framework is pending approval by Health Canada. An example of a rare disease drug is Kalydeco, for cystic fibrosis costing $325,000 annually. The duration of a rare diseases can be indefinite resulting in annual reoccurring claims.

Specialty Drugs

Why is specialty drug production increasing when it is more expensive to produce?

Due to key advances in drug developments, Drug companies can make drugs that "target" a disease. Molecular targeting specifically targets the molecular pathway that causes the disease. Biomarkers created by a disease allows for drug therapies to be developed as precision medicine. Precision medicine is targeting a specific gene sequence.

Some examples;

- Multiple Sclerosis
- Hepatitis C
- Genetic Disorders
- Cancer
- HIV
- Plaque Psoriasis
- Rheumatoid Arthritis
- Growth Hormone
- Crohn's Disease
- Ulcerative Colitis

Major Pipeline Drugs – 2016 to 2018

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DRUG	USAGE	ANNUAL COST (EST)
Ibrance	Breast Cancer	$82,000
Cotellic	Melanoma	$100,000
Zepatier	Hepatitis C	$60,000
Uptravi	Pulmonary Hypertension	$50,000
Orkambi	Cystic Fibrosis	$300,000
PCSK9 Inhibitors	High Cholesterol	$9,000
MAB (monoclonal antibodies)	Esosinophilic Asthma	$30,000
Entresto	Heart Failure	$2,900
MAB (monoclonal antibodies)	Migraine	$7,500

Why are Speciality Drugs more expensive?

Speciality drugs target a smaller population, R&D costs, more expensive to manufacturer (biologic drugs take up to 100 different steps involving living organisms costing significantly more to develop than traditional drugs).

Manufactures will price according to what the market will bear. Many drugs are breakthrough therapies and the fact that there are no close substitutes in the marketplace, manufacturers are able to command high prices keeping in mind they treat serious or life threating illnesses.

*** the cost of specialty drugs are 25 times more expensive than traditional drugs. Specialty drugs account for only 2% of total claims however, account for 26% of total drug costs.*

Forecasting the future growth of Speciality Drugs

- ✓ Specialty drugs will be the driver behind growth in drug spending
- ✓ Specialty drugs are expected to rise to 8% to 10% 2016
- ✓ FDA – expects to approve 60% of new drugs within 3-5 years
- ✓ By 2018 – it is estimated that 7 out of the 10 top selling drugs (by dollar value) will be speciality drugs

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Speciality drugs defined in annual costs

- ✓ New class of innovative Biological medications called PKSK9 inhibitors. Used to lower low density lipoprotein (LDL or 'bad' cholesterol. Expected to cost $7,000 annually compared to current therapy of $400.
- ✓ Cancer drugs – a class of cancer drugs showing particular promise in clinical trials is called **programmed death – 1 receptor monoclonal antibodies (PD-1).** It activates the body's immune system to target tumor cells, these drugs have shown promise in treating a variety of cancers including; melanoma, lung and bladder cancers. The annual cost - $150,000.

What can be done to manage these specialty drugs to protect the private drug plan system?

Evidence Based Formularies- drugs that provide a high level of effectiveness at a low cost are reimbursed at a higher amount compared to those that do not provide the same level of effectiveness.
This can result in a 10% plan savings.

Mandatory Generic Substitution- ensures brand name drugs that have a generic available are dispensed. This can result in a 1.5 to 3.8 % in plan savings.

Dispensing Fee Frequency limits and Caps- dispensing medications at larger levels, ie. 90 days to reduce the number of claims paid by the drug plan. Also utilizing a dispensing fee cap will reduce the amount paid on each drug claim submitted.
This can result in 10 to 19 % in plan savings.

Initiatives that target specialty drugs- processes to ensure the right medication is being used at the time by the right candidate, known as Prior Authorization. Working with preferred provider networks to maximize favorable pricing. Implementing programs to increase patient adherence.

In Conclusion;

- There is a disproportional increase in expensive medications to treat common chronic - conditions.
- Existing strategies to manage drug plans are under utilized by plan sponsors.
- Innovations in medication management and adherence is needed to sustain the drug plans for the future.