Understanding the potential of generic substitution
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Generic pricing reforms and the availability of generics for blockbuster drugs coming off patent has helped slow the increase in drug plan costs for plan sponsors. However, there are opportunities to further maximize savings, depending on the generic substitution rider that the plan has in place.

Three generic substitution riders are available:

1. **Generic substitution = No**
   - Q: What does this mean?
   - A: There is no generic substitution rider on the policy.
   - Q: What is paid for a prescription for a brand name product when a generic alternative is available?
   - A: If the pharmacy dispenses the brand, it is reimbursed at the brand name price; if the pharmacy dispenses the generic, it is paid at the generic price.

2. **Generic substitution = Yes**
   - Q: What does this mean?
   - A: There is a generic substitution rider on the policy.
   - Q: What is paid for a prescription for a brand name product when a generic alternative is available?
   - A: If the pharmacy dispenses the brand, it is reimbursed at the generic price; if the pharmacy dispenses the generic, it is paid at the generic price.
   
   However, if the physician writes “No Substitution” on the prescription, and the pharmacy indicates this during the submission process, the brand is reimbursed at the brand drug price.

3. **Generic substitution = Always**
   - Q: What does this mean?
   - A: There is a mandatory generic substitution rider on the policy.
   - Q: What is paid for a prescription for a brand name product when a generic alternative is available?
   - A: Both brand and generic products are always reimbursed at the generic price; prescriptions where the physician writes “No Substitution” are reimbursed at the generic price.

   However, the plan member may pay the difference in price between the brand and generic and receive the brand name product.

**Private Plan Use of Generic Substitution**

While plan sponsors understand the concept of generic substitution, 27% of plan members are still covered by policies without any generic substitution rider (Figure 1). The increase in the “Always” generic substitution rider from 19% to 36% over the last year comes from groups who were previously using generic substitution and now want to ensure their savings are maximized. This trend is expected to continue.
The Impact of the Generic Substitution Rider on Brand and Generic Drug Use

TELUS Health classifies drugs as:
- single source – includes brand name products which are patent protected;
- brand – brand name product without patent protection and a generic alternative is available; or
- generic – generic alternative product.

Table 1: Percent of paid claims and eligible prescriptions: single-source, brand and generic drug products

<table>
<thead>
<tr>
<th>Year</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013 YTD - October</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013 YTD - October</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Source</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand</td>
<td>42.2%</td>
<td>39.9%</td>
<td>36.6%</td>
<td>35.0%</td>
<td>66.9%</td>
<td>66.9%</td>
<td>65.7%</td>
<td>66.1%</td>
</tr>
<tr>
<td>Generic</td>
<td>7.0%</td>
<td>6.8%</td>
<td>7.0%</td>
<td>7.0%</td>
<td>5.2%</td>
<td>5.4%</td>
<td>6.0%</td>
<td>6.3%</td>
</tr>
</tbody>
</table>

The brand share of paid claims has remained relatively stable but there has been a substantial increase in the generic share of paid claims and a decline in paid claims for single source products - reflective of the loss of patent protection for high volume products and re-classification from single source to brand. Despite the decline in the proportion of claims for single-source products (now at 35% YTD October 2013), the proportion of eligible costs that single-source products represents remains at two-thirds (66.1% YTD October 2013).

By considering the multisource environment, defined as brand + generic, the brand share of paid claims has remained relatively stable at approximately 11% across Canada (Figures 2 and 3).
Figure 2: Brand share of multisource (brand + generic) paid claims

![Brand Share of Paid Claims when Generic Alternative Is Available (Canada, Ontario, Quebec)](image)

Figure 3: Brand share of multisource (brand + generic) paid claims

![Brand Share of Paid Claims when Generic Alternative Is Available (Canada, Western Canada, Atlantic Canada)](image)
Use of No Substitution Prescriptions
As noted above, the plan design for generic substitution comes into consideration when the physician indicates “No Substitution” on the patient’s prescription.

When we look further into the data, there has been an increase in the percentage of prescriptions written by the physician as “No Substitution,” a trend that is occurring in all regions.

Nationally, the percentage of prescriptions written and dispensed as “No Substitution” has increased from 8.7% of brand name products in multisource product categories at the beginning of 2012 to 9.9% as of October 2013 (Figures 4 and 5). The most significant increases in “No Substitution” claims have occurred in Ontario (Figure 3) and Atlantic Canada (Figure 4).

What can explain the apparent increase in “No Substitution” claims? There are several reasons why a physician might indicate “No Substitution” for keeping a plan member on a brand name drug when a generic exists:

- **Allergies** – prescribers may want to keep a patient on a brand name drug due to allergies to the non-medicinal ingredients.

- **Critical dose drugs** – while Health Canada has stricter bioequivalence requirements, there is anecdotal evidence (note: there is limited clinical study evidence) to demonstrate that a patient may have suboptimal outcomes when switched from the brand to generic or switched from one generic to another generic.

- **Patient choice cards** (Figure 6) – these permit the patient to receive the brand name drug with the cost difference between generic drug cost and brand drug cost billed to the pharmaceutical company; note: this option is available to the patient without “No Substitution” written by the physician on the prescription, however, it would require the patient to request the brand from the pharmacy.

- **Patient confusion** – the launch of more generic alternatives could lead to an increased risk of generic-to-generic switching if a patient switches pharmacies often or if the pharmacy changes the generic supplier and could result in patient confusion or a misunderstanding of their current drug therapies.

- A combination of any of the above.

There likely has not been an increase in allergies, and Health Canada has standards in place to assess bioequivalence for drugs, including consideration of drug products that require more rigorous application of testing criteria including critical dose drugs, so neither of these offer a reasonable explanation for the increase in “No Substitution”.

A more likely contributing factor is the increased availability and use of the patient choice cards that permit the patient to receive the brand name drug, with residual amounts being billed to the pharmaceutical manufacturer. The increase in these cards is driven by a number of factors that include the patent cliff and a paucity of blockbuster drugs to take over for the patent expiring blockbusters. The influx of these cards has led the Ontario Pharmacists Association to produce a guidance document for pharmacies that defines the three categories of cards (Figure 6).
Figure 4: Brand name products dispensed because physician wrote “No Substitution”

![Figure 4: Brand name products dispensed because physician wrote “No Substitution”](image1.png)

Figure 5: Brand name products dispensed because physician wrote “No Substitution”

![Figure 5: Brand name products dispensed because physician wrote “No Substitution”](image2.png)
Figure 6: Patient choice/drug loyalty drug cards (Source: Ontario Pharmacists Association)

**PATIENT CHOICE (“BRAND LOYALTY”) DRUG CARDS**

**A PRIMER FOR PHARMACISTS**

**SUBJECT:** In the last few years, assorted types of cards to offset cost burden to patients have been introduced as defined below. This document focuses on the complexity of PATIENT CHOICE CARDS that are intended to cover the cost differential for patients between a specified branded drug product and its interchangeable generic counterpart.

### Types of Cards on the Market

<table>
<thead>
<tr>
<th>Drug Sample Cards</th>
<th>Patient Assistance</th>
<th>Patient Choice Cards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Also known as “smart cards”</td>
<td>Also known as “co-pay cards”</td>
<td>Also known as Brand Loyalty Cards or Manufacturer’s Coupon Cards</td>
</tr>
<tr>
<td>Intended to provide patients with a small introductory and (usually) complimentary supply of a new (trial) medication</td>
<td>Intended to offset or reduce the out-of-pocket patient costs not covered by the patients’ public or private drug plan</td>
<td>Designed to facilitate patient choice of medication therapy by eliminating the financial gap between generic and brand name medications</td>
</tr>
<tr>
<td>Claims are processed through a third party adjudicator on behalf of the manufacturer who absorbs the drug cost, mark-up and the pharmacy dispensing fee, up to a defined maximum</td>
<td>Typically, the cards are available for high cost drugs, for which the out-of-pocket costs could present a significant financial challenge for the patient</td>
<td>Patients can choose to obtain or switch to the branded drug instead of its lower cost interchangeable brand, with little or no additional out-of-pocket expenditure</td>
</tr>
<tr>
<td></td>
<td>Claims are processed through a third party adjudicator on behalf of the brand name drug manufacturer who absorbs the costs up a defined maximum</td>
<td>Cards cover the difference in cost between what the drug plan will pay (typically the generic price) and the actual cost of the brand name drug, up to a defined maximum</td>
</tr>
</tbody>
</table>

### The Potential Savings Available from Maximizing Generic Substitution

Plan sponsors, including plan sponsors without any generic substitution rider, have benefited from lower generic prices because of public mandatory generic substitution policies and the practice of pharmacists to preferentially dispense the generic product.

**Are there additional savings still available?**

The methodology for the analysis was to re-calculate the eligible ingredient cost substituting the generic unit cost for the brand unit cost, if higher, with the difference from the original eligible ingredient cost representing potential savings.

Savings of up to 11% or up to $87.4 million (YTD October 2013) of the eligible ingredient cost for brand and generic drugs remain available to plan sponsors from increased use of generic alternatives. The most significant savings are in Quebec, with the elimination, in January 2013, of Best Available Price for 15 years (BAP 15), the Quebec policy through which the Quebec government reimbursed the brand name drugs for a 15-year period from the listing of the drug on the formulary, even if generic products become available. The elimination of this Quebec policy will continue to help plan sponsors capture the savings.

While it will never be realistic to expect all available savings to be captured due to factors in the environment, there are savings available to plan sponsors that include a generic substitution rider on the policy. The highest level of savings is available to plan sponsors who include an ALWAYS generic substitution rider on the policy.
Summary
Opportunities exist in all regions to increase the use of generic alternatives and decrease plan costs.

A generic substitution rider on the policy is essential for taking the first step to capture savings from lower cost generic alternatives after the patent on the brand name product expires.

But only with an ALWAYS generic substitution rider on the policy can the increase of "No Substitution" prescriptions be managed and the savings from lower cost alternatives be maximized.

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References
1 According to Health Canada, critical dose drugs are defined as drugs where comparatively small differences in dose or concentration lead to dose- and concentration-dependent, serious therapeutic failures and/or serious adverse drug reactions which may be persistent, irreversible, slowly reversible or life threatening, which could result in in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity or death.

2 Health Canada has two guidance documents: Conduct and Analysis of Comparative Bioavailability Studies and Comparative Bioavailability Standards: Formulations Used for Systemic Effects. The purpose of these documents is to update and consolidate 11 existing Health Canada documents related to the conduct and analysis of comparative bioavailability studies and the standards to be met in those studies in order to comply with relevant sections of the Food and Drug Regulations. These guidance documents also outline that drugs may have one or more characteristics that require modifications to the standards; modified-release dosage forms, drugs with serious toxicity within the normal dosage range, drugs exhibiting non-linear pharmacokinetics, drugs with a terminal elimination half-life of more than 24 hours, drugs with an important time of onset of effect or rate of absorption, critical dose drugs, combination products, drugs with highly variable pharmacokinetics, drugs with measurable endogenous levels, drugs for which pharmacodynamic studies are appropriate alternatives to comparative bioavailability studies of oral dosage formulations, drugs for which urine drug concentration data is used (available on the Internet at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-id/bio/gd_cbs_ebc_id-eng.php)
Information for life

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