What Effects do Provincial Drug Plan Coverage Policies for New Drugs have on Patterns of Use and Cost?

November 2003
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ISSUE

Concern over the cost and appropriate use of new drugs has led provincial drug plans to look at various policies for drug coverage. While some drugs are covered as a general benefit (GB), and will be routinely paid for, others are covered only when information is provided to demonstrate use in specific clinical situations. This information is transmitted to the drug plan by 1) codes written on the prescription, as is done for Ontario’s limited use (LU) program, or 2) through a more complex process that involves obtaining drug plan approval before a prescription filled, as is done for special authority (SA) programs in British Columbia and Ontario. Little is known about how these policies affect drug utilization or cost.

More information on specific policies can be obtained at: www.gov.on.ca/health/english/program/drugs/odbf/odbf_mn.html and www.healthservices.gov.bc.ca/pharme/sa/saindex.html.

STUDY

This study examined the use of two new classes of drugs – cyclo-oxygenase-2 (COX-2) inhibitors and atypical neuroleptics – prescribed to persons aged 65 years and older under different drug coverage policies in Ontario and British Columbia (BC). Cyclo-oxygenase-2 (COX-2) inhibitors (a type of non-steroidal anti-inflammatory drug or NSAID) and atypical neuroleptics are more costly than their predecessors.

NSAIDs

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely prescribed for the treatment of inflammation and pain associated with arthritis and other musculoskeletal conditions, and are among the most commonly used medications in the world. While NSAIDs have many benefits, some users experience gastrointestinal side effects and a few develop serious complications, such as ulcers, often without pain or other warning symptoms.

COX-2 inhibitors were approved for use in Canada in 1999, based on studies suggesting fewer upper gastrointestinal side effects when compared with therapy using conventional NSAIDs. In Ontario and BC, conventional NSAIDs are covered as GB drugs. In Ontario, COX-2 inhibitors are covered under the LU program; while in BC, they are covered as SA drugs.

Neuroleptics

Neuroleptics or “antipsychotics” were developed primarily to treat symptoms of schizophrenia and related psychotic disorders, although they are also used for short-term management of behavioural disturbances, such as verbal or physical aggression or agitation in patients with severe dementia. A new generation of antipsychotics, called “atypical” neuroleptics, was introduced in Canada in the early 1990s, promising fewer side effects than conventional neuroleptics. Side effects of greatest concern in the elderly are sedation and postural hypotension, associated with an increased risk of falls.

Among the atypical neuroleptics available in Canada (clozapine, olanzapine, risperidone, and quetiapine), only risperidone is approved for the treatment of behavioural and psychological

Provincial drug plan coverage abbreviations

| GB | General benefit. No restriction. |
| LU | Limited use in Ontario. Specific clinical conditions must be met for coverage. |
| SA | Special authority programs in BC and Ontario. Requires drug plan approval before the prescription is filled. |
symptoms of dementia (BPSD). Conventional and atypical neuroleptics are listed as GB in Ontario. In contrast, in BC, conventional neuroleptics are listed as GB, and the majority of atypical neuroleptics are covered under the SA program, with some having been approved as GB.

**ANALYSIS**

Drug claims data were used to study oral NSAID and neuroleptic prescriptions to persons aged 65 years or over that were paid for by provincial drug plans, and excluded prescriptions paid for by federal or private insurance plans or by patients themselves. In a separate analysis, BC's PharmaNet database was used to add information about the number of NSAID prescriptions to seniors paid for by sources other than BC's provincial drug plan.

**FINDINGS**

**NSAIDs**

In Ontario, quarterly oral NSAID use per senior rose by 70% in the year following approval of COX-2 inhibitors (celecoxib and rofecoxib) as LU products (Figure 1), leading to a near tripling of quarterly NSAID costs (Figure 2). In contrast, there was virtually no increase in NSAID utilization or provincial drug plan cost per senior when COX-2 inhibitors were granted SA status in BC. These results highlight the impact of the early, rapid uptake of COX-2 inhibitors in Ontario versus an apparently lower, more sustained level of use among BC seniors, as reflected by prescriptions paid by the provincial drug plans.

*Figure 3* replicates Figure 1 for a subset of NSAIDs (See Notes, Figure 3 for details.), and gives data on prescriptions paid for by sources other than BC's provincial drug plan. Before the introduction of COX-2 inhibitors, there was little payment outside the provincial plan for NSAIDS for the elderly. When COX-2 inhibitors were released, covered only under a restrictive SA policy in BC, there was a rapid increase in NSAID prescriptions paid for outside the provincial plan. Total utilization under and outside the provincial plan in BC was still much lower than under the Ontario provincial plan. These findings underline the usefulness of BC's PharmaNet data in helping drug plan managers to understand the potential consequences of public benefit plan restrictions on overall access.

Different drug coverage policies for COX-2 inhibitors in Ontario and BC has led to markedly different patterns of overall use of, and cost to, public plans. Further research is required to quantify whether the greater use of COX-2 inhibitors has improved the health of Ontarians.

**Neuroleptics**

In BC, where atypical neuroleptics were initially granted SA status, quarterly neuroleptic prescriptions paid for by the provincial government remained relatively stable (Figure 4). At the same time, from April 1997 to September 2002 the ratio of prescriptions for conventional to atypical neuroleptics fell in BC from 3.6 (4,399/1,369) to 0.2 (1,933/9,433) and quarterly plan spending on neuroleptics grew from $0.70 to $3.01 per senior (or about $0.10 per senior per quarter, Figure 5). Thus, even without increased use, a gradual shift from conventional to predominantly atypical neuroleptics has led to substantial growth in drug plan spending in BC.

These findings contrast with a near tripling of the rate of neuroleptic prescriptions and a cost growth of $0.20 per senior per quarter in Ontario, where atypical neuroleptics are available without restriction. Over the same period, the ratio of prescriptions for conventional to atypical neuroleptics fell in Ontario from 11.9 (78,795/6,608) to 0.2 (46,352/224,287), and provincial drug
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Plan spending on neuroleptics increased six-fold (from $0.77 per senior per quarter to $5.15). Thus, the combination of increased use and a relatively larger shift toward atypical neuroleptics has resulted in even greater cost growth in Ontario, than in BC. Here, atypical neuroleptic prescription accelerated after the introduction of quetiapine, and then again after Health Canada's approval of risperidone for BPSD (Figure 4). Similar changes were not observed in BC when, for example, risperidone and quetiapine were reclassified from SA to GB. These results suggest that factors other than plan design, such as promotional activity, may also be implicated. Studies are needed to determine the levels of “off-plan” use of atypical neuroleptics, and to assess the incremental risks and benefits of increased use in seniors.

CONCLUSIONS

Drug coverage policies have a marked impact on utilization and spending from provincial drug plans. More restrictive policies may shift costs to private insurers and consumers. The effect of such policies on overall access and health outcomes warrants further study.
Fig 2. Quarterly Oral NSAID Cost to the Provincial Drug Plans in Ontario and BC

Notes: 1) Reference-based pricing in effect for NSAIDs in BC. 2) The per prescription copayment was increased from the dispensing fee (up to an annual maximum of $200) to $25 max. (and an annual max. of $275).

Ontario
- $13.30 per Senior (Total: $20.1 mil)
- Celecoxib & Rofecoxib approved as LU products in Ontario

BC
- $1.74 per Senior (Total: $0.94 mil)
- New co-payment policy in BC

Ontario
- $4.52 per Senior (Total: $6.7 mil)

BC
- $1.43 per Senior (Total: $0.75 mil)

Fig 3. Quarterly Oral NSAID Prescriptions per Senior by Province and Payer

Notes: 1) This figure incorporates prescriptions for celecoxib, diclofenac, diclofenac-misoprostol, etodolac, ibuprofen, meloxicam, nabumetone, naproxen, and rofecoxib; which represent about 85% of prescriptions for oral NSAIDs during the study period. 2) Data for off-plan use not available for Ontario.

Ontario
- Prescriptions Paid by the Provincial Drug Plan

BC
- All Prescriptions

Celecoxib & Rofecoxib approved as SA products in BC

Celecoxib & Rofecoxib approved as LU products in Ontario

Rofecoxib launched in Canada

Celecoxib launched in Canada

Prescriptions Paid by Non-Provincial Drug Plans & Patients
**Fig 4. Quarterly Neuroleptic Prescriptions Paid by the Provincial Drug Plans in Ontario & BC**

Notes: 1) Risperidone was approved as an SA product in BC and a GB in Ontario in 1994. 2) BPSD = behavioural and psychological symptoms of dementia.

**Fig 5. Quarterly Neuroleptic Cost to the Provincial Drug Plans in Ontario and BC**

Notes: 1) Risperidone was approved as an SA product in BC and a GB in Ontario in 1994. 2) BPSD = behavioural and psychological symptoms of dementia.