Private payer perspective matters:

Guidance for developing a pharmaceutical budget impact analysis.

Part 1 of a 2-part series.

Introduction

Although Canada is recognised as having a publicly funded health care system, this primarily relates to physician visits and hospital services. Canada is unique in high income countries with universal health coverage in that this does not relate to prescription drugs. In 2017, private health insurance covered approximately 22 million Canadians (60%) and paid for $12.3 billion (45%) of all drug purchases in Canada (1). Spending is expected to increase with expensive cancer and rare disease therapies dominating the drug pipeline where private plans will be primary coverage (2). Private payers want to balance access to effective therapies for employees and their families with the implementation of strategies to manage spending to ensure long-term plan sustainability. As a result, TELUS Health has implemented an Enhanced Drug Review Process which incorporates clinical efficacy, cost-effectiveness and financial impact in making formulary listing recommendations for private payers/carriers and decisions for TELUS Health's managed formularies. Having an accurate estimate of the expected cost associated with reimbursing a new drug is referred to as a Budget Impact Analysis (BIA). A BIA consists of mathematical modelling to predict the financial impact of adopting a new drug, incorporating data and assumptions on drug cost, drug cost offsets, market share, disease incidence and relevant population.

While there are some published guidelines for conducting BIAs from the public payer perspective, there is a lack of consistency to the methods used in BIA models developed by drug manufacturers. This guidance document is intended to help those producing BIAs for private payers, in an attempt to provide more credibility and relevancy for private plan sponsors, standardize economic information, methods and reporting. The ultimate goal is to facilitate well-informed decision-making specific to private payers. BIAs submitted to private payers should follow the recommendations set out in this document as well as best practices published by the Patented Medicines Pricing Review Board (PMPRB) in 2020 (3). Use of a standard approach increases transparency in the process and confidence that the results are representative of differences between drug costs as opposed to differences in methodologies. Furthermore, using a standard approach will help ensure efficient reviews and provides a framework for complex assessments and novel scenarios. These guidelines will be reviewed and revised as necessary.

Transparency and justification of assumptions

When developing a budget impact model, the data and assumptions used as inputs drive its reliability and validity. It is important to provide enough detail so that these inputs can be validated. For example, market share expectations should be clearly explained and properly justified. As well, lack of transparency, poorly organized and overly complex models are common issues in submitted BIAs. The simplest model design that generates accurate results should be preferred.

Alignment/consistency

The submitted model should reflect the reimbursement request (i.e., Health Canada indication) being made and should be aligned with the clinical data evidence supporting the submission. Both the cost-effectiveness analysis and the BIA are expected to be consistent with each other and driven by the same evidence and core assumptions. For example, assumptions used for drug costing (e.g., time on treatment, dosing, compliance) in the pharmacoeconomic model should be consistent with those used in the BIA. Similarly, the comparators within the pharmacoeconomic model should at minimum reflect the drugs which are forecasted to be displaced within the BIA.

Unique needs of private payers

Below is a list of items that would help to make the BIA more representative of the private payer perspective.

Modeling approach

When reasonably feasible, the target population that defines the market should be based on actual claims data (claims-based), since it is more precise and reflects real-world experience. This would apply, for example, when a new drug enters an existing class and is expected to essentially displace other drugs. However, a claims-based approach is not always practical or appropriate – for example, certain drugs may have multiple indications which may not be distinguishable within claims data. In that case, using an epidemiological (patient-based) approach or a hybrid claims-based/epidemiological approach are alternatives.

Eligible population

It is common that submitted BIAs apply disease prevalence and incidence reflecting the entire Canadian population, without regard to the specific demographics covered by private payers. This can result in erroneous epidemiological projections given that the privately insured population has different demographics relative to the general public. Epidemiological projections should reflect private drug plan beneficiaries, whom are generally of working age with/without spouses and underage dependents. For example, a rare genetic disease primarily affecting children may have higher prevalence under private drug plans versus the general population. Conversely, a cancer occurring mostly in older patients is not likely to affect as many private drug plan beneficiaries compared to public plans. However, one should not simply exclude the population aged 65 years and over – some may have private retiree benefits. A review of the 2019 TELUS Health book of business indicates that there is a sizable number of beneficiaries aged 65 years and older contributing to a significant portion of claims. For example, it was estimated that if a drug is not publicly covered, then up to 25% of seniors may have private retiree benefits (4). As a result, it should not be simply assumed that individuals aged 65 and over would automatically be covered by public payers. This is especially the case in certain provinces such as British Columbia and Manitoba which no longer provide comprehensive coverage for older patients (5).

When estimating the target population for the private payer, it is preferred to use Canadian age-specific disease incidence/prevalence and then separate the incidence/prevalence numbers by ages 0-64 and aged 65+ per 100,000. A good rule of thumb would be to assume that 90% of private drug plan beneficiaries are aged 0-64 and 10% are aged 65 years and over. The weighted incidence/prevalence for the private payer can be used in the BIA model.

Appropriate comparators

Incorporating the appropriate comparator drugs is key to ensuring the model is relevant to plan administrators. Comparators need to reflect the current standard of care in Canada for the target population (e.g., off-label use when relevant). Drugs that are not used in actual practice should be excluded. As each payer may have different drugs covered on their formularies, it is relevant to provide the option in the model to easily remove/include comparator drugs (e.g., drugs provided in hospitals may not be covered by the private insurer). The model should also allow flexibility for adjusting the proportion of the increased market share for the product requesting listing that is derived from each of the current comparators, untreated cases, and, if applicable, clinical trial medications.

Because a BIA intends to provide the most accurate forecast of the expected impact of reimbursing the new drug on the private payer's budget, the base case analysis should consider that publicly funded comparators cost nothing to the private payer. This is common for IV drugs used in oncology. While this implies that the budget impact will be increased, an insurer is able to contextualize this type of situation in their review.

Unless the new drug is already covered by public plans, concurrent public reimbursement should not be assumed in a private drug plan BIA, neither should generic pricing/loss of patent exclusivity of the new drug after a certain number of years. A table summarizing the predictions of public coverage and/or genericization could be provided in the report for consideration as context.

Estimating the market share

Although in some cases, the introduction of a new product will displace other treatments, there are a number of scenarios in which this is not the case and the full impact of the new treatment on the market should be reflected within the BIA.

In estimating the market share for the new product, it important to consider how the introduction of the product and company promotional activity may influence the disease diagnosis and treatment. For example, if a large proportion of cases are currently assumed to be undiagnosed, and the company/key opinion leaders are engaged in activities to promote improved diagnosis, the potential impact of increased treated disease should be reflected within the BIA. Similarly, if many cases are not treated due to the current lack of an effective treatment, the introduction of an effective treatment into the market will likely reduce this proportion substantially. Assumptions regarding market share should also reflect the assumptions and the results of the pharmacoeconomic model. If the model suggests the new drug is a substantive improvement on current therapies then this should be reflected in the magnitude of the assumed captured market share.

As there is often significant uncertainty in the estimated impact on the market, the BIA model should be sufficiently flexible to allow alternative assumptions to be considered. As noted previously, all assumptions should be supported by evidence and provided with the submission so they can be validated.

Drug prices

Given that private plan drug prices are not publicly available, using Ontario values is a good proxy and representative of most Canadian provinces. However, in Canada, there is broadly speaking a drug pricing duality; there is generally one (lower) price in Québec and one price for all the other provinces. As a result, Québec pricing should be available as an alternative to ensure relevance to Québec-specific insurers. When Ontario public prices are not available, a good alternative would be to use list prices published by drug wholesalers.

Pharmacy upcharges

Due to the varying schedules of pharmacy upcharges across provinces, the base case BIA should exclude them (i.e. markups and dispensing fees). The user should have the option in the model of including/excluding pharmacy upcharges broadly representative of the Canadian private market (e.g. 8% wholesale markup, 8% retail markup capped at $250, approximately $10 dispensing fee).

Non-drug formulary costs

A drug BIA should solely include costs supported by private drug plans. Costs for medical interventions, devices or procedures that are not funded through a private drug plan are outside the scope of a BIA. In case that some of these non-drug costs are funded by a private payer through other vehicles, like extended health benefits for example, it may be informative to include them as a scenario analysis.

Drug dosing

For a claims-based analysis, the daily dose should be calculated directly from the data. In other cases, when there are several comparators, it is better to apply the dosing schedule as found in the product monograph and then adjust for relative dose intensity, when applicable. Adjusting for relative dose intensity observed in the randomized controlled trial is fine as long as this adjustment is applied to all drugs, not just the new drug (reducing its cost) as this introduces bias.

Reporting

BIAs should be transparent, accessible and justify all assumptions that have been made. The limitations of the analysis should be explicitly noted.

Input parameters and results should be presented annually in their disaggregated and aggregated forms. Results should match 12-month periods starting from the expected reimbursement date (not calendar years) for at least three years in the future.

The base case analysis should present the budget impact ''per life covered''. An impact per defined number of lives can also be provided as ancillary information (e.g., per 100,000, per million).

The number of sensitivity analyses should be limited to scenarios where uncertainty may have a material impact on results. A fully unlocked and modifiable model should be provided to allow plan administrators to assess alternate scenarios.

Conclusion

Budget impact analyses are important for the evaluation of financial risk of the reimbursement of new pharmaceuticals for payers. Simply submitting the same economic studies that have been prepared for public reimbursement (i.e., CADTH/INESSS) to the private payer is not appropriate and leads to significant interpretive uncertainty. It is important to understand who the "private payer" is in order to have an appreciation of the perspective required. It is ultimately the employer or plan sponsor, who purchases a benefits package, among which is the drug plan, with the goal of keeping their workforce healthy and productive as well as attract and retain employees. The insurer acts as an administrative body that pays for drugs and manages benefits on behalf of the plan sponsor through the premiums collected from them. Insurers implement plan design or formulary changes to manage costs, impacting access and coverage to plan members. As a result, insurance companies are increasingly becoming more sophisticated in formulary management and well versed in health technology assessment and health economic evaluation methodologies. Thus, it behooves manufacturers to conduct their economic analyses from the private payer perspective. This would improve the payer's confidence in the validity and relevance of the submitted evidence and can only help to improve the drug review process without much extra effort on the manufacturer's part. This guidance document serves to promote consistency and relevance for the design of a BIA for manufacturer's submissions to the private payer.

Authors

Daria O'Reilly, PhD, MSc

- Lead Health Economist, Pharmacy Consulting, Health Benefits Management, TELUS Health, Toronto, ON
- Associate Professor (PT), Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, ON

Richard Lavoie, MSc

- Practice Lead – Health Economics, Synergyx Consulting Inc., Montréal, QC

Contributors

Doug Coyle, PhD

- Professor, School of Epidemiology and Public Health, University of Ottawa, Ottawa, ON

Kathryn Coyle, BScPhm and MSc

- Health Economics Research Group, College of Health and Life Sciences, Brunel University London, Uxbridge

Bobby Currie, BScPharm, RPh

- Leader, Clinical Pharmacy Services, Canada Life Assurance Company, Winnipeg, MB

Dr Harris Iacovides BSc, BScPharm, MSc, PharmD

- Drug Strategy, Health and Ability Strategy, Group Customer, Canada Life Assurance Company

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