
Budget Impact Assessment

*for the
Alberta Drug Benefit List*

Version 7: October 2012

Please note the BIA Completion Checklist included in this form must be completed and signed. Failure to do so may result in the product submission being deemed incomplete.



Points for Consideration:

1. The information presented in this Budget Impact Assessment (BIA) form may:
 - assist the Alberta Health Expert Committee on Drug Evaluation and Therapeutics in making a recommendation and the Minister of Health in making a decision to add a product to the Alberta Drug Benefit List (ADBL)
 - serve as a starting point for the negotiation of Product Listing Agreements (PLA), where applicable.
2. All fields must be completed. Failure to do so may result in the Drug Product submission being deemed incomplete and/or delays in potential listing decisions.
3. Alberta specific data (e.g. prevalence of disease states, projected market shares, etc) should be used, where possible. If Alberta specific data is not available, other sources may be used if justification is provided, sources are adequately referenced and assumptions stated.
4. A three-year time horizon is required for all projections.
5. All projections should be for Alberta Health sponsored drug programs only (e.g. not the entire health care system). The Alberta Health drug programs include the drug program for seniors, widows/widowers and non-group coverage.
6. Additional information may be appended to the Budget Impact Assessment Form if necessary.

Directions for Use:

BIA Completion Checklist

- Upon completion of the BIA, the 'Checklist' must be completed and signed. Failure to do so may result in the Drug Product submission being deemed incomplete.

Section 1: Drug Product Information

- Complete the table listing all relevant comparators. If there are non-drug alternatives (e.g. surgery) then state these in this section. Indicate the category of listing sought and the proposed criteria.

Section 2: Indication/Dosage Information

- List all indications that have been proposed for reimbursement eligibility along with their recommended dosage and duration.
- If treatment or dosage guidelines currently exist for a specific indication, please ensure that they are adequately referenced.

Section 3: Total Prescription Cost/Patient/Month for Each Indication

(Based on Recommended Dose)

- Total prescription cost/patient/month should be based on the acquisition cost of the Drug Product, the inventory allowance and the dispensing fee as described in the *Alberta Blue Cross Pharmacy Agreement Schedule of Prices*. Please note that the *Schedule of Prices* represents the maximum allowable price/prescription that can be charged. The schedule is as follows:

<i>Effective date (04/01/05)</i>	<i>Inventory Allowance</i>	<i>Dispensing Fee</i>
Actual Acquisition Cost of \$0.00 - \$74.99	\$0.71	\$10.22
Actual Acquisition Cost of \$75.00 - \$149.99	\$2.00	\$15.53
Actual Acquisition Cost of \$150.00 or greater	\$5.03	\$20.94

- The actual acquisition cost (AAC) is defined as the cost of the drug borne by the pharmacy; therefore, the AAC may include a wholesaler distribution allowance (markup), if applicable.
- All Drug Products that are available only via wholesaler should utilize a wholesaler distribution allowance of 7.5% in their calculations.
- Those Drug Products available from both manufacturer and wholesaler should NOT include 7.5% in their calculations.
- In the case of medications where recommended duration of use is less than 30 days (e.g. antibiotics), this should be specified and the cost calculated accordingly. For example, if the recommended duration of use is 14 days, then the cost should be based on the AAC of 14 days supply of the Drug Product, the inventory allowance and a dispensing fee.
- In the case of insulin and oral contraceptives, the prescription cost does not exceed the actual acquisition cost of the Drug Product x 5/3.

- For injectable Drug Products other than insulin, the prescription cost does not exceed the actual acquisition cost of the injectable Drug Product x 5/3, to a maximum of \$100.00 more than the actual acquisition cost of the injectable Drug Product.
- In general, the net prescription cost to Alberta Health sponsored drug programs should be calculated as 70% of the total prescription cost calculated above. The remaining 30% would reflect the patient's co-payment portion. However, if 30% of the prescription cost exceeds \$25.00, Alberta Health will pay for the balance of the prescription cost that exceeds \$25.00 and this should be reflected in the calculations.

Section 4: Prevalence of Disease State(s)/Condition(s) for which the Drug Product is Indicated

- List the prevalence of the disease state and/or indication for which the Drug Product is intended for the total Alberta population and for the population covered by the Alberta Health Programs.
- Data should be Alberta specific and not simply an extrapolation of Canadian national data or data from other provinces to the Alberta population. If Alberta specific data is not available, a justification for why this is so must be provided.
- It is recognized that prevalence data may not be available in some instances. In such cases, prevalence data may be extrapolated from claims data. Justification must be provided for calculating prevalence in this manner and necessary assumptions and sources appropriately cited.

Section 5: Projected Market in Alberta

- List projected market shares as total number of patients and percentage of the total market for each disease state/indication.
- Market shares for years one, two and three must be reported for a full calendar year (12 months) after proposed listing date. (e.g., April 2012 to April 2013)
- Clearly state where and what proportion of the proposed market is coming from (e.g. new patients, cannibalization of another product's market share). Cite all relevant references.

Section 6: Direct Prescription Costs

- Calculate the direct prescription costs that Alberta Health sponsored drug programs will incur if the product is listed according to the category of listing sought (refer to Section 1).
- Prescription costs should be an extension of the prevalence of the disease state/indication, the projected market share of the product for the disease state/indication and the prescription costs to the Alberta Health sponsored drug programs as calculated in Section 3.
- List all of the assumptions used in calculating the values and cite all relevant references.

Section 7: Incremental Prescription Costs (Savings)

- Calculate incremental prescription costs or savings that Alberta Health would incur if the product were listed according to the category of listing requested.
- List all of the assumptions used in calculating the values and cite all relevant references.
- Use the lowest cost alternative (LCA) price for relevant drug comparators where applicable.

Section 8: Sensitivity Analyses

- Calculate one-way and/or multi-way sensitivity analyses for direct prescription costs and incremental prescription costs (savings).
- An explanation of the methods used to calculate the sensitivity analyses must be included as well as the assumptions used in calculating the values. Cite all relevant references.

Section 9: Conclusions

- Clearly state the conclusions of the BIA and the proposed cost impact to the Alberta Health sponsored drug programs.

Section 10: Additional Information

- Include any additional information that is relevant to the assumptions or calculations.
- Utilization data from other jurisdictions or countries where the product is reimbursed are welcomed.
- Append treatment or dosage guidelines if applicable and ensure that they are adequately referenced.
- Please comment on whether this listing of this medication will have a significant impact on health care services (e.g., laboratory testing, diagnostic testing, etc).
- Additional BIAs completed by the manufacturer that do not conform to this BIA format, but provide additional information, are welcome and may be appended to this form.

BIA Completion Checklist

- Upon completion of the BIA, the 'Checklist' must be completed and signed. Failure to do so may result in the product submission being deemed incomplete and/or delays in potential listing decisions.

General

- All fields and sections of the BIA form are complete.
- Alberta specific data is used.
 - Justification is provided where Alberta specific data has not been used.
- Projections are for a 3-year time horizon.
- Projections are for Alberta Health (Alberta Health) sponsored programs, ONLY (i.e. seniors, widows/widowers, non-group).

Sections 1 – 10

- All relevant comparators are stated, including non-drug alternatives.
- All approved indications are listed, with recommended dosages and durations.
- Total prescription cost/patient/month (or shorter duration, where applicable) is calculated, for each indication, based on recommended dose and using **CURRENT** inventory allowances and dispensing fees as listed on page 2
 - Calculated using actual acquisition cost (AAC) (including allowable wholesale mark up, if applicable) + inventory allowance + current dispensing fee.
 - For insulin and oral contraceptives, the prescription cost does not exceed 5/3 x the AAC of the drug product.
 - For injectables other than insulin, the prescription cost does not exceed 5/3 x the AAC of the drug product, to a maximum of \$100 more than the AAC of the drug product.
- Net prescription cost to Alberta Health is 70% of the total prescription cost, plus the balance of the co-payment portion (30%) that exceeds \$25 (i.e. patient co-pay maximum is \$25).
- Disease state prevalence information, specific to Alberta and Alberta Health, is provided.
 - Justification is provided where Alberta specific data has not been used.
- Projected market is reported as total number of patients, and percentage of total market.
- Market is projected for a full calendar year (12 months) from proposed listing date.
- Source of market, and proportion of market from each source, are reported.
- Direct prescription costs are reported as the Alberta Health portion.
 - Projections are calculated using prevalence, market share and prescription costs stated.
 - All assumptions are listed, and references cited.
- Incremental prescription costs are reported for Alberta Health.
 - All assumptions are listed, and references cited.
 - LCA price is used as the AAC for comparators, where applicable.
- One-way or multi-way sensitivity analyses are conducted.
 - For direct prescription costs.
 - For incremental prescription costs.
 - An explanation of the sensitivity analysis methods is included.
 - All assumptions are listed, and references cited.
- The conclusions of the BIA are clearly stated.

Optional

- Additional relevant information may be attached (**optional**):
 - Utilization from other jurisdictions
 - Treatment or dosage guidelines
 - Comments on whether listing will significantly affect health care spending
 - Additional BIAs appended that do not conform to this format (if applicable)

Signature: _____ Date: _____

Section 1: Drug Product Information

Brand name:	
Generic name:	
Dosage form(s)/strength(s) and associated cost per unit:	
Therapeutic Category/PTC:	
Relevant comparators (including non-drug alternatives):	
Category of listing sought (e.g., unrestricted benefit, special authorization, restricted benefit) and <u>proposed criteria</u> (if applicable).	

- Complete the table listing all relevant comparators (including non-drug alternatives).
- Indicate category of listing and proposed criteria (if applicable).

Section 2: Indication/Dosage Information

Indication(s) for which listing is sought:	Usual recommended dose/duration per indication

- List all indications proposed for reimbursement eligibility, recommended dose and duration.
- Reference treatment or dosage guidelines (if applicable).

**Section 3: Prescription Cost/Patient/Month for Each Indication
(Based on Recommended Dose)**

Indication	Total prescription cost/patient/month	Net Cost to Alberta Health/patient/month

- Total prescription cost/patient/month should be based on the CURRENT acquisition cost of the medication, inventory allowance and dispensing fee. Wholesale mark-up and distribution fees should be included in the cost if applicable. See Directions for Use (Section 3) for further information.
- Net cost to Alberta Health should be calculated as 70% of the prescription cost. The remaining 30% would reflect the patient's co-payment portion. However, if 30% of the prescription cost exceeds \$25.00, Alberta Health will pay for the balance of the cost that exceed \$25.00. This should be reflected in the calculations.
- In the case of medications where the recommended duration is less than 30 days, this should be specified and the costs calculated accordingly.

Section 4: Prevalence of Disease State(s)/Condition(s) for which the Drug Product is Indicated

A) Total Alberta Population

	Prevalence in Alberta (Number of Patients)		
Disease State/ Indication	Year 1	Year 2	Year 3

B) Population Covered by Alberta Health

	Prevalence in Alberta (Number of Patients)		
Disease State/ Indication	Year 1	Year 2	Year 3

- List the prevalence of the disease state/indication for which the medication is intended for the Alberta population and for those covered by the Alberta sponsored drug benefit programs.
- Demographic data may be accessed via the Alberta Health Statistical Supplement.

Please list all relevant assumptions and cite references.

Section 5: Projected Market in Alberta

A) Total Alberta Population

	Projected Market in Alberta (Total number of patients)		
Disease State/ Indication	Year 1	Year 2	Year 3

	Projected Market in Alberta (% Market Share)		
Disease State/ Indication	Year 1	Year 2	Year 3

B) Population Covered By Alberta Health

	Projected Market in Alberta (Total number of patients)		
Disease State/ Indication	Year 1	Year 2	Year 3

	Projected Market in Alberta (% Market Share)		
Disease State/ Indication	Year 1	Year 2	Year 3

- List projected market shares as total number of patients and percentage of total market for each disease state/indication.
- Market shares for years one, two and three must be reported for a full calendar year.
- Clearly state where the proposed market is coming from (e.g., new patients, cannibalization of another product's market share).
- All tables must be completed.

Please list all relevant assumptions and cite references.

Section 6: Direct Prescription Costs

	Direct drug costs to Alberta Health		
Disease State/ Indication	Year 1	Year 2	Year 3

- Calculate the direct prescription costs that the Alberta Health sponsored drug benefit programs would incur if the product were listed according to the category of listing sought.
- Prescription costs should be an extension of the prevalence of the disease state/indication, the projected market share of the product and the prescription costs to the Alberta Health sponsored drug benefit program as calculated in Section 3.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 7: Incremental Prescription Costs (Savings)

	Incremental prescription costs (savings) to Alberta Health		
Disease State/ Indication	Year 1	Year 2	Year 3

- Calculate the incremental prescription costs or savings that Alberta Health would incur if the product were listed according to the category of listing sought.
- Use the lowest cost alternative (LCA) price for all relevant drug comparators where applicable.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 8: Sensitivity Analyses

A) Sensitivity Analyses for Direct Prescription Costs to Alberta Health

	Range of Direct Prescription Costs		
Disease State/ Indication	Year 1	Year 2	Year 3

B) Sensitivity Analyses for Incremental Prescription Costs (Savings)

	Range of Incremental Prescription Costs (Savings)		
Disease State/ Indication	Year 1	Year 2	Year 3

- Calculate one-way and/or multi-way sensitivity analyses for the direct prescription costs and incremental prescription cost (savings).

List all of the assumptions used in calculating the values and cite all relevant references.

Section 9: Conclusions

- Clearly state all of the conclusions of the budget impact assessment and the overall proposed cost impact to the Alberta Health sponsored drug programs.

Section 10: Additional Information

- Include any further information relevant to assumptions or calculations
- Utilization data from other jurisdictions or countries where the product is reimbursed are welcomed.
- Append treatment or dosage guidelines if applicable. Please ensure they are adequately referenced.
- Please comment on whether the listing of this medication will have a significant impact on health care services (e.g. laboratory testing, diagnostic testing, etc.)
- Please comment on potential indications for which coverage may be sought in the future.
- Additional BIAs completed by the manufacturer that do not conform to this BIA format, but provide additional information, are welcomed and may be appended to this form.