

Budget Impact Analysis

For The Manitoba Health, Seniors and Active Living

Manitoba Drug Benefits and Interchangeability Formulary

Points for Consideration:

1. The information presented in this form may:
 - assist the Manitoba Drug Standards and Therapeutics Committee (MDSTC) in making a recommendation to the Minister of Health in making a decision to add a product to the Manitoba Drug Benefits and Interchangeability Formulary
2. All fields must be completed.
3. Manitoba specific data (e.g. prevalence of disease states, projected market shares, etc.) should be used, where possible. If Manitoba 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 the Manitoba Health, Seniors and Active Living Pharmacare program only (e.g. not the entire health care system). Additional projections may be requested for drugs that significantly impact other Manitoba Provincial Government sponsored drug programs.
6. Additional information may be appended to the Budget Impact Analysis Form if necessary.

Directions for Use:

Section 1: Drug Information

- Complete the table listing all relevant comparators. If there are non-drug alternatives (e.g. surgery) please state these alternatives in this section. Indicate the category of listing sought and the proposed criteria. Additionally, please indicate the category of listing sought in other Provincial and Territorial jurisdictions.

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: Drug Cost/Patient/Month for Each Indication (Based on Recommended Dose)

- Total drug cost/patient/month should be based on the actual acquisition cost (AAC) of the medication. The actual acquisition cost (AAC) is defined as the cost of the drug borne by the pharmacy; therefore, the AAC may include a wholesaler markup, if applicable.
- 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 medication.

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

- List the prevalence of the disease state and/or indication for which the medication is intended for the total Manitoba population and for the population covered by the Manitoba Pharmacare Program. (A breakdown for all Manitoba Provincial Government sponsored drug programs is requested.)
- Data should be Manitoba specific and not simply an extrapolation of Canadian national data or data from other provinces to the Manitoba population. If Manitoba specific data is not available, a justification for why this is so must be provided.

Section 5: Projected Market in Manitoba

- 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 1, 2010 to March 31, 2011)
- 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 Drug Costs

- Calculate the direct drug costs that the Manitoba Pharmacare Program will incur if the product is listed according to the category of listing requested (refer to Section 1).
- Drug 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 drug costs to the Manitoba Health, Seniors and Active Living 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 Drug Costs (Savings)

- Calculate incremental drug costs or savings that Manitoba Health, Seniors and Active Living 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 relevant drug comparators where applicable.

Section 8: Sensitivity Analyses

- Calculate one-way and/or multi-way sensitivity analyses for direct drug costs and incremental drug 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 budget impact analysis and the proposed cost impact to the Manitoba Pharmacare Program. (A breakdown of data is required when a significant impact to other Manitoba Provincial Government sponsored drug programs is realized.)

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 the listing of this medication will have a significant impact on health care services (e.g., laboratory testing, diagnostic testing, etc.)
- Additional budget impact analysis completed by the manufacturer that do not conform to the BIA (Budget Impact Analysis) format, but provide additional information, are welcomed, and may be appended to this form.

Section 1: Drug Information

Brand name:	
Generic name:	
Dosage form(s)/strength(s) and associated cost per unit:	
Therapeutic Category:	
Relevant comparators (including non-drug alternatives):	
Category of listing requested [e.g. Part 1 (unrestricted), Part 2 (restricted benefit), Part 3 (Exception Drug Status), 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 requested:	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: Drug Cost/Patient/Month for Each Indication (Based on Recommended Dose)

Indication	Total drug cost/patient/month	Net Cost to Manitoba Health/patient/month

- Total drug cost/patient/month should be based on the actual acquisition cost of the medication. Wholesale mark-up and distribution fees should be included in the cost if applicable. See Directions for Use (Section 3) for further information.
- 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 is Indicated

A) Total Manitoba Population

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

B) Population Covered by Manitoba Health, Seniors and Active Living

	Prevalence in Manitoba (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 Manitoba population and for those covered by the Manitoba Pharmacare program.
- Demographic data may be accessed via the Manitoba Health, Seniors and Active Living Website <http://www.gov.mb.ca/health/annstats/> and Federal Governments statistics page <http://commerce.statcan.ca/english/commerce/> .
- Ensure demographic data is from the above-mentioned sources; if not, clearly state all assumptions and data sources.

Please list all relevant assumptions and cite references.

Section 5: Projected Market in Manitoba

A) Total Manitoba Population

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

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

B) Population Covered By Manitoba Health, Seniors and Active Living

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

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

- 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, absorption of another product's market share).
- All tables must be completed.

Please list all relevant assumptions and cite references.

Section 6: Direct Drug Costs

Direct drug costs to Manitoba Health, Seniors and Active Living			
Disease State /Indication	Year 1	Year 2	Year 3

- Calculate the direct drug costs that the Manitoba Pharmacare program would incur if the product(s) were listed according to the category of listing sought. (A breakdown for all Manitoba Provincial Government sponsored drug programs is also requested.)
- Drug costs should be an extension of the prevalence of the disease state/indication, the projected market share of the product and the drug costs to the Manitoba Pharmacare program as calculated in Section 3.

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

Section 7: Incremental Drug Costs(Savings)

Disease State /Indication	Incremental drug costs (savings) to Manitoba Health, Seniors and Active Living		
	Year 1	Year 2	Year 3

- Calculate the incremental drug costs or savings that Manitoba Pharmacare program would incur if the product(s) were listed according to the category of listing sought. (A breakdown for all Manitoba Provincial Government sponsored drug programs is also requested.)
- Use the lowest cost 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 Drug Costs to Manitoba Health, Seniors and Active Living

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

B) Sensitivity Analyses for Incremental Drug Costs(Savings)

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

- Calculate one-way and/or multi-way sensitivity analyses for the direct drug costs and incremental drug 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 analysis and the overall proposed cost impact to the Manitoba Pharmacare program. (A breakdown of data is required when a significant impact to other Manitoba Provincial Government sponsored drug programs may be realized.)

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.
- Comment on whether the listing of this medication will have a significant impact on health care services (e.g. laboratory testing, diagnostic testing, etc.)
- Comment on potential indications for which coverage may be sought in the future.
- Additional budget impact analysis completed by the manufacturer that provide valuable additional information but do not conform to the BIA format, should be appended to this form.