Manitoba Health

GUIDE TO DEVELOPING A UTILIZATION MANAGEMENT AGREEMENT (UMA) BUSINESS CASE

BUSINESS CASE FORMAT AND CONTENTS

Interested drug manufacturers can submit their Business Cases to:

Manitoba Health
Drug Management Policy Unit
3016 - 300 Carlton Street
Winnipeg, Manitoba R3B 3M9

Attention: Director, Drug Management Policy Unit

Email: Jeff.Onyskiw@gov.mb.ca

With a copy to:

Kathy McDonald
Manitoba Health
Provincial Drug Programs
1014 - 300 Carlton Street
Winnipeg, Manitoba R3B 3M9

Email: Kathy.Mcdonald@gov.mb.ca

in both paper and electronic (MS WORD) formats by setting out their information in the following order:

1) *Executive Summary*

Include an Executive Summary that summarizes the manufacturer's discussion of each of the items listed in sections 2 to 11, inclusive, of this Guide, as follows:

- Describe when and how the subject drug product is usually prescribed (e.g. product indications).

- Identify and describe any gaps or factors in utilization of the subject drug product that may contribute to patients not achieving the maximum health outcome.

- Summarize the manufacturer's total yearly dollar value proposition to Manitoba Health (MH) should the subject drug product be listed as a Manitoba Drug Benefit or included on the Manitoba Drug Interchangeability Formulary, or both, including the net projected benefit to MH that would result from the manufacturer's expenditure projections and any utilization management or other initiative that measures patient health outcomes.

- An overview that includes:

  (i) the benefit status (i.e. Part 1, 2 or 3 of the Specified Drugs Regulation 6/95 under The Prescription Drugs Cost Assistance Act, C.C.S.M c. P1115) that would be requested by the manufacturer for the subject drug product, if and when a UMA is finalized;

  (ii) any binding commitments that the manufacturer would be willing to make in favour of MH under a UMA having a minimum duration of three (3) years, including a risk mitigation commitment (see: section 6 of this Guide) and a promotional commitment (see: section 7 of this Guide);

  (iii) any provision for the renegotiation, renewal or extension of a UMA after three (3) years; and

  (iv) any provision that would limit the continuation of a UMA over a three (3) year period.

2) *Clinical profile for the drug product*

- In the case of a generic drug product, a list of all current indications and the anticipated timeline(s) for any future indications, if applicable, over a three (3) year period.

- Summarize all clinical and pharmacoeconomic (i.e. health outcomes) results of any published clinical trials.

- Compare the value of the subject drug product versus other comparable, existing drug therapies.

- Describe the positioning of the subject drug product in current medically endorsed, Canadian clinical practice guidelines.

3) *The benefit status that would be requested by the manufacturer for the subject drug product, if and when a UMA is finalized*

NOTE: identify Part 1, 2 or 3 of the Specified Drugs Regulation 6/95 under The Prescription Drugs Cost Assistance Act, C.C.S.M c. P1115

4) *Expenditure projection/ forecast*

- A yearly forecast of Government of Manitoba total expenditures under *Manitoba Pharmacare* and all other provincially funded drug programs

over three (3) years for both the subject drug product and the interchangeable drug category in which the subject drug product would be included. Each yearly forecast would include

(i) the total projected cost to the Government of Manitoba; and

(ii) the net expenditure impact (whether cost additive or cost saving) to the Government of Manitoba.

- Any key forecasting assumptions made by the manufacturer, such as market growth and benefit status, and how these assumptions would be addressed in a UMA.

5) *Cost impact to the provincial health care system, Net Present Value*

Definition: dollar-adjusted Net Present Value (NPV) means a cash flow projection over a *3 time horizon* (i.e. three year cash flow discounted net present value) that includes relevant healthcare costs such as hospitalizations stays, emergency room visits, and surgical procedures.

- Include a Table that compares the NPV under a base case or status quo to the manufacturer's proposed drug utilization management or other initiative that measures patient health outcomes over a three (3) year period.

- Summarize the manufacturer's rationale to support its proposed system-wide cost savings (e.g. improvements in compliance)

6) *Risk Mitigation*

- Definition: Risk Mitigation means a manufacturer's binding commitment to assume a portion of the costs incurred by the Government of Manitoba under *Manitoba Pharmacare* and the other provincially funded drug programs should the manufacturer's expenditure projection/ forecast (see: section 4 of this Guide) be exceeded.

- A manufacturer's proposed binding obligations in favour of the Government of Manitoba under a UMA, including a detailed description of mechanisms for Risk Mitigation if cost and/ or sales projections for the subject drug product

are exceeded in any of the three (3) years while the UMA is in effect, and, if applicable, on the cost to the Government of Manitoba in an interchangeable drug category.

7) *Promotional commitment*

- A detailed description of the manufacturer's mechanisms/strategies to facilitate appropriate utilization and/or prescribing by medical practitioners in the Province of Manitoba and a willingness by the manufacturer to commit to disclose all promotional materials and strategies to MH.

8) *Utilization management or other initiatives to measure health outcomes*

- Describe in detail any investments, mechanisms, and strategies by the manufacturer to facilitate that appropriate utilization occurs and/or to measure patient health outcomes which may include, but is not limited to, the following:

  (i) aligning the promotion of and the optimal use of the subject drug product in the Province of Manitoba with medically endorsed, Canadian Clinical Practice Guidelines;

  (ii) improving the value-based utilization of healthcare services in the Province of Manitoba;

  (iii) improve patient health outcomes; and

  (iv) measuring real-world effectiveness, improvements in quality of life, and health outcomes for patients in the Province of Manitoba.

9) *Any provisos or limitations (e.g. early termination) to the continuation of a UMA over a three (3) term*

NOTE: if none, indicate in your Business Case "no provisos or limitations"

10) *Critical path or timelines*

NOTE: this would be in relation to the timing for listing or inclusion of the drug product on the Manitoba Drug Benefits and Interchangeability Formulary and the timing for the manufacturer to carry out its commitments, including Risk Mitigation, under a UMA.

11) *Any additional information that a manufacturer would ask MH to consider.*

REVISED: January 2013