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CRITERIA FOR LISTING DRUG PRODUCTS ON THE CALGARY TYPE A CONTINUING CARE HOME (CCH) FORMULARY

The following criteria are applied to drug listing requests reviewed by the Calgary Type A CCH Pharmacy and Therapeutics (P&T) Committee. These are general criteria intended to be applied flexibly, considering each individual request. They may be modified or adapted as the situation may require. Not all criteria will apply to each case. The same criteria may be adapted when a Formulary drug is reviewed for removal or change to its funding criteria.

The criteria are:

1. A drug product listed in the Health Canada Drug Product Database with a Drug Identification Number (DIN), or a natural health product listed in the Licensed Natural Health Products Database with a Natural Product Number (NPN). [1][2]
2. A demonstrated need for the Type A resident population (e.g., unique action or indication for use)
3. Clinical efficacy (unequivocal effectiveness in the elderly and/or Type A CCH resident population)
   - Positive clinical patient outcomes
   - Favorable population health outcomes
   - Clear therapeutic advantage over other listed agents
   - Presence of mitigating patient factors such as compliance or mode of administration
4. Resident safety (a reasonable safety profile or at least a predictable risk)
   - Risk/Benefit ratio is acceptable
   - Toxicity is low or reasonable
5. Cost-effectiveness and Stewardship (a clear efficiency to the entire system of care)
   - Equitable and sustainable
   - Unit cost, volume of use
   - Direct and indirect cost savings
   - Environmental impact

[1] Health Canada Drug Product Database
[2] Health Canada Licensed Health Canada Licensed Natural Health Products Database

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- Access to bulk purchasing
- Alternate funding
- Public coverage in other jurisdictions or care streams

The Committee will evaluate the request using the five criteria outlined above. Ideally, the requester/applicant will undertake a drug review for the agent requested and submit it to the Committee for consideration. Such reviews must include template headers addressing each of the five criteria. The Committee will use the Drug Review in its deliberations and may ask for further information from the applicant. If a drug review is not feasible or applicable (e.g. drug discontinued by manufacturers), the Committee will deliberate using the available information.

Various sources will assist the Committee in its work including Library Services, formulary reviews completed by other services, published guidelines and consensus statements, clinical studies, individual practitioners known to have expertise in the specific area, Health Canada advisories, and Canada's Drug Agency. The likely best evidence[i] will assist the Committee in informing its discussions and eventual decision.

Coverage for Alternate Strengths and Formulations Not Listed on Formulary

Where a drug listed on the Formulary is available in alternate strengths and formulations, funding for the non-listed drug product or strength is not included. The Committee, either self-directed or upon request using the ***FPP-02 a – Requests for Additions, Deletions or Changes to the Formulary*** form, may review the product for a line-extension listing.

FPP-02A -- REQUESTS FOR ADDITIONS, DELETIONS OR CHANGES TO THE FORMULARY (see Appendix 1)

Purpose

- To facilitate the role of medical practitioners, prescribers, pharmacy providers, and Calgary CCCH operators in the selection of medications listed on the Calgary Type A CCH Formulary.
- To provide a process and sample template for Formulary additions, deletions, or changes.

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Process

1. To request a drug product addition, deletion or change to the Formulary Drug Listing, the requestor should at a minimum complete **Part A** of the form ***FPP-02a – Requests for Additions, Deletions or Changes to the Formulary***, and submit to the Committee via email at cc.drugmanagement@albertahealthservices.ca for consideration.
   - A request may be submitted by medical practitioners, prescribers, or other health care professionals practicing in Calgary Type A CCHs, or a member of the P&T Committee.
2. As much as possible, the requestor should also complete **Part B - Drug Review** based on the five criteria: unique need, action or indication for Type A CCH population, efficacy, acceptable safety and toxicity profile, and cost effectiveness.
3. The request will be brought forward as an agenda item to a future P&T Meeting at the next available opportunity
4. The Committee may supplement the information in the Drug Review if needed and may ask the requestor for further information regarding the request.
5. The Committee will use the information in its deliberations using evidence-based thinking and decision making.
6. The Committee will approve, amend, or deny the request. If the drug product is to be added to the Formulary Listing, it will be categorized as either open Formulary listing (F), Special Authorization (SA), or Restricted Status (RS). Therapeutic substitutions (TS) may be applied.
7. The Committee will complete **Part C – P&T Committee Decision Summary**, and notify the requestor of the decision.

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APPENDIX 1: SAMPLE FORM

Formulary Additions, Deletions, or Change Request

The requestor should submit via or fax to ISFL Drug Management at:
cc.drugmanagement@albertahealthservices.ca **OR** fax to 403-943-0232.

PART A

Request for Additions, Deletions, or Changes to the Calgary Type A CCH Formulary

Part A to be completed by medical staff and/or other health care professionals practicing within a Calgary Type A Continuing Care Home (CCH)

Request for Addition/Deletion/Change to the Type A CCH Formulary – Part A	
☐ Addition ☐ Deletion ☐ Other (e.g. line extension Request Date: Reason/Trigger for Request:	Drug Product Name: Drug Active Ingredient(s): Strength(s), Dosage Form(s): Route of Administration: Drug Identification Numbers(s): Generic availability:
What is the unique need, action, indication for this drug product request in the Type A CCH resident population? Indication(s) for Use, Special Precaution(s), Usual dose: Advantages Over Existing Formulary Drugs:	
Clinical Efficacy:	
Resident Safety Profile:	
Cost-Effectiveness/Sustainability:	
Proposed Listing Criteria:	
Requested by: Contact Information: Conflicts of Interest with request:	

PART B

DRUG REVIEW

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Part B to be completed by the requester when possible. The P&T Committee may assist with completing Part B to support committee deliberations.

Drug Review – Part B	
What is the Health Canada Indication(s)? Relevant off-label indication(s)?	
Is the requested indication(s) on-label?	
Is the indication(s) supported by current practice guidelines?	
Mechanism of Action	
What is the usual dose & frequency of administration for this indication?	
Please describe any special administration requirements, e.g. special protocols, equipment, or supplies.	
Please describe any special monitoring requirements, e.g. lab tests specific to the requested product.	
Which formulary product(s) could be used as a treatment alternative for the requested indication? Formulary | Alberta Health Services	
What advantages does this product have over formulary alternatives?	
Drug Use Evaluation (annual cost, rates of use, typical NF decision)	
Environmental/Climate considerations	

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Efficacy	
What type of literature is available to support the requested listing? *Please attach articles & include in reference section*	☐ Systematic review (SR) of randomized controlled trials (RCT) ☐ Individual RCT ☐ SR of cohort studies ☐ Individual cohort study ☐ SR of case-control studies ☐ Individual case-control study ☐ Case series ☐ Expert opinion
What kinds of outcomes have been studied for the requested indication(s)? *Please attach articles & include in reference section*	☐ mortality ☐ morbidity ☐ quality of life ☐ surrogate markers
Which residents are most likely to benefit from the use of this product?	
Will this product be used as first, second or third-line therapy?	First-line ☐ Second-line ☐ Third-line
Safety	
Are there any safety risks associated with the use of this product?	☐ Administration issues ☐ Product packaging and labeling ☐ Look-alike or sound-alike name ☐ Other ☐ None identified Please describe:
Which residents should not take this product?	
Which residents should be cautious about taking this product?	
Comparative safety to alternatives	

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Economics	
Compared to currently available alternatives, please rate the relative drug cost of this product.	☐ Less ☐ Neutral ☐ More ☐ Unsure Comments:
Compared to currently available alternatives, rate the relative impact of this product on overall healthcare costs (e.g., length of stay, readmission rates, lab/diagnostic testing, additional equipment or staffing costs, other ancillary costs.	☐ Less ☐ Neutral ☐ More ☐ Unsure Comments:
Unit Cost of requested product **(a)** *(specify cost source and date)*	
Average # of dosage units per day (**b**) (b = # of units per dose X frequency; based on usual dosage)	
Cost per day per patient (**c**) = a x b	
Is pharmacoeconomic literature available?	Yes ☐ No ☐ *If "yes", please attach articles & include in reference section*
Alberta Health Drug Benefit List (AH DBL) Status Alberta Health - Drug Benefit List	☐ Yes ☐ No
Canada's Drug Agency (CDA) Status Canada's Drug Agency | CDA-AMC	☐ Yes ☐ No
Alberta Health Services Provincial Drug Formulary	☐ Yes ☐ No
References	

PART C

P&T Committee Decision Summary

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Part C to be completed by the P&T Committee following a decision on the request

P&T Committee Decision Summary – Part C			
☐ Addition ☐ Deletion ☐ Change Request Date:	Completion Date:		
Drug Product Name: Drug Active Ingredient(s): Strength(s), Dosage Form(s): Route of Administration: Drug Identification Numbers(s)			
Criteria	**Summary**	**Met**	**Unmet**
Unique action, indication or need for the product in the Type A CCH resident population		☐	☐
Clinical efficacy		☐	☐
Patient Safety		☐	☐
Cost Effectiveness/Sustainability		☐	☐
☐ List on the Calgary Type A CCH Formulary Type of Listing: Criteria: Rationale: ☐ Do NOT list on the Calgary Type A CCH Formulary Rationale: ☐ Other decision:			

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Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

** OCEBM Table of Evidence Working Group = Jeremy Howick, Iain Chalmers (James Lind Library), Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, Hazel Thornton, Olive Goddard and Mary Hodgkinson*

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"The 2011 Oxford CEBM Evidence Levels of Evidence (Introductory Document)". Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

Jeremy Howick, Iain Chalmers, Paul Glasziou, Trish Greenhalgh, Carl Heneghan, Alessandro Liberati, Ivan Moschetti, Bob Phillips, and Hazel Thornton.
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[i] Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning