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Criteria for Listing Drug Products on the LTC Formulary

The following criteria apply to drug product submissions reviewed by the Long Term Care Pharmacy and Therapeutics Committee. They are general criteria only and are intended to be applied flexibly, having regard to each individual case. They may be modified or adapted as the situation may require. Not all criteria will apply to each case. The same criteria may be applied when the formulary is reviewed to remove agents. The criteria are:

1. Drug Identification Number

2. Unique action or indication for use
    a. Not a 'me-too' agent.

3. Clinical Efficacy (unequivocal effectiveness in the LTC population)
    a. Positive clinical patient outcomes
    b. Favorable population health outcomes
    c. Clear therapeutic advantage over listed agents
    d. Presence of mitigating patient factors such as compliance or mode of administration

4. Patient Safety (a reasonable safety profile or at least predictable risk)
    a. Risk/Benefit ratio
    b. Toxicity

5. Cost-effectiveness (a clear efficiency to the entire system of care)
    a. Unit cost
    b. Direct and indirect cost savings
    c. Volume of use
    d. Access to bulk purchasing

The committee will decide on the addition or removal of an agent using the five criteria outlined above. Ideally a drug review will be undertaken for each agent and submitted to the committee for consideration. Such reviews must have template headers that address each of the five criteria. The committee will use the algorithm (see attached) in its deliberations. It may ask for further information regarding specific applications. If a drug review is not feasible or possible the committee will deliberate using the five criteria listed.

Various sources will assist the committee in its work including Regional Drug Information service, regional pharmacy services, published guidelines and consensus statements, clinical studies, individual practitioners known to have expertise in the specific area, Health Canada advisories, the Common Drug Review The highest level of evidence [1] will assist the committee in informing its discussions and eventual decision.

Evidence based medicine: a definition

The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Evidence-based medicine does ***not*** *mean "cook-book" medicine, or the unthinking use of guidelines. It* ***does*** *imply that evidence should be reasonably readily available in an easily understood and useable form.*

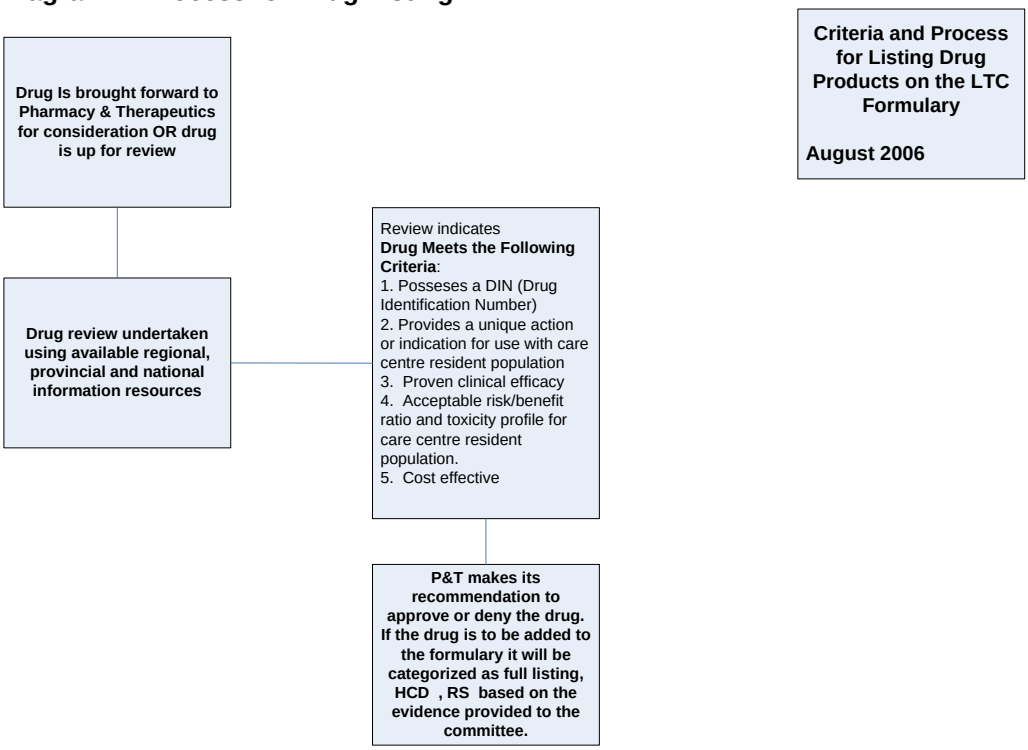
Bandolier :Evidence based thinking about health care http://www.jr2.ox.ac.uk/Bandolier/index.html

Ranking of 'best available evidence' or Levels of Evidence

1. Strong evidence from at least one systematic review of multiple well designed randomised controlled trial
2. Strong evidence from at least one properly designed randomised controlled trial of appropriate size
3. Evidence from well designed trials such as non randomised trials, cohort studies, time series or matched case controlled studies
4. Evidence from well designed non-experimental studies from more than one centre or research group
5. Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees

Criteria for Listing Drug Products on the LTC Formulary

Diagram 1 Process for Drug Listing



Product review will include the following "Inclusion Criteria for Listing"

1. Drug Identification Number
2. Unique action or indication for use

3. Clinical efficacy in the long term care population as evidenced through positive clinical patient outcomes; favourable population health outcomes; clear therapeutic advantage over listed agents; presence of mitigating patient factors such as compliance or mode of administration
4. Patient safety is reasonable and predictable in that risk/benefit ratio is acceptable and the toxicity levels are low or reasonable
5. Cost effective in relation to unit cost, evidence of direct and indirect cost savings, volume of use and access to bulk purchasing.

P&T Drug List Decision Summary Tracking Tool (for P&T Committee Use Only)

Drug
Recommended by
Drug Review Completed (attached)

Criteria	Evidence Summary	Met	Unmet
Review included all available information			
DIN			
Unique action or indication			
Clinical efficacy Positive clinical patient outcomes Favourable population health outcomes Clear therapeutic advantage Presence of mitigating patient factors			
Patient Safety Risk/Benefit ratio acceptable Toxicity profile acceptable			
Cost Effective Unit cost Direct and indirect cost savings Volume of use Access to bulk purchasing			

P&T RECOMMENDATION

Date: _____

☐ Recommend for Inclusion in LTC Formulary
☐ Recommend NOT to include in LTC Formulary
Reasons for concern:

_____
_____
_____

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☐ Request for further information prior to decision
Reasons for concern:

_____
_____
_____

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Addendum: Coverage for alternate strengths and formulations not listed on formulary

Where the LTC formulary attempts to be a comprehensive listing of all medications covered for long-term care residents, it should be recognized that newer strengths and formulations of a drug product may not be specifically listed in the formulary medication listing. In these cases, it is not the intention of the P&T committee to force residents to use the "listed" doses.

Please note that different strengths and formulations of formulary drug products may be covered if ALL of the below criteria are met:

1) The different formulations are considered equivalent and interchangeable
2) They have the same route of administration
3) The "unlisted" formulation is not associated with a significantly higher cost
4) Usage is based upon therapeutic need, convenience to patient and staff, and supply demands