

Vendor Frequently Asked Questions (FAQ)
**Alberta Health Services (AHS) Provincial Drug Formulary, and Provincial Drugs
and Therapeutics Committee (DTC) Processes**

Background

The Alberta Health Services (AHS) Provincial Drug Formulary and AHS Correctional Facilities Drug Formulary Supplement are continually updated listings of pharmaceutical products approved for use in the Acute Care and Correctional Facility settings by the AHS Provincial Drugs and Therapeutics Committee (DTC). The membership of the DTC has broad clinical and geographic representation. A formulary decision to select pharmaceutical products, with criteria of use if applicable, is based on literature evidence of efficacy, safety, and cost-effectiveness, which supports the provision of consistent medication therapy across the province. The Provincial Drug Formulary and Supplement apply to inpatient hospitals, community health sites, and provincial correctional facilities.

How can a request regarding the formulary status of a medication be made?

All queries regarding a medication's formulary status, quality assurance and/or safety issues will be referred to the *Director, Drug Procurement and Stewardship* or *Manager, Pharmacy Procurement and Inventory*. The vendor may be provided with AHS Provincial Drug Formulary and Supplement status for their products, but not for any competitors' products.

Who can request additions or changes to the AHS Provincial Drug Formulary?

Only prescribers and pharmacists within AHS may request changes to the AHS Provincial Drug Formulary and Supplement(s). The requester must complete and sign the applicable 'Formulary Changes Request' form and send it to the AHS Pharmacy Drug Utilization and Stewardship Team.

Types of formulary changes include:

- ☐ Additions
- ☐ Line Extensions
- ☐ Therapeutic Interchange or Restriction Change
- ☐ Appeal of Previous Exclusion/Resubmission
- ☐ Formulary Deletion

How is a medication request reviewed for the AHS Provincial Drug Formulary and Supplement(s)?

The Drug Utilization and Stewardship (DUS) pharmacists will review the request and complete a formulary evaluation. Clinical stakeholder feedback is obtained from across the provincial zones if required, followed by discussion and decision at appropriate committee levels. The DTC review process is intended to be fair, objective, and transparent.

Some of the criteria DTC considers in making recommendations to AHS Executive include:

- ☐ clinical studies/scientific published literature
- ☐ therapeutic advantages and disadvantages relative to current formulary alternatives
- ☐ overall “cost-effectiveness” relative to current formulary alternatives

DTC may recommend to AHS Executive that a drug be open-listed on the AHS Provincial Drug Formulary and Supplement(s), be listed with criteria or conditions, or not be listed (and possibly not provided).

Occasionally a recommendation may be deferred pending further clarification of information or other ~~facts~~

Newly Marketed Drugs Not Provided

In early 2019, the provincial Drug and Therapeutics Committee and Clinical Operations Executive Committee approved the formulary status and procedure: Not Reviewed – Do Not Provide (NRDNP). Under this procedure, all new drugs or dosage forms which receive Health Canada Notice of Compliance (NOC) and are marketed after January 1, 2019, will be designated as *Not Reviewed Do Not Provide (NRDNP)* formulary status **and will not be provided within AHS facilities until a formulary review has been completed and the drug receives a positive listing on the AHS Provincial Drug Formulary and/or Supplement(s)**. In exceptional circumstances, NRDNP/URDNP drugs could be requested and provided to a patient via the non-formulary process following review and approval by the *Drug Utilization, Stewardship and STEDT Manager* or *Drug Procurement and Stewardship Director*. For hospital-only drugs, the review will be automatically initiated with a prioritized timeline of 3 to 6 months. For drugs with the potential to be used outside of hospital, the review will be completed once the Alberta Drug Benefit List (ADBL) decision is finalized, and upon receipt of a formulary request or at the request of DTC.

How are changes to the AHS Provincial Drug Formulary and Supplement(s) communicated?

Changes to the AHS Provincial Drug Formulary and Supplement(s) are internally communicated to AHS physicians and staff through a provincial DTC Update newsletter.

External communication to vendors regarding a medication’s formulary status will be issued by the *Director of Drug Procurement and Stewardship* or *Manager of Pharmacy Procurement and Inventory* following receipt of a specific vendor query regarding their products’ formulary status. Formulary status of competitors’ drugs will not be provided.

What are the AHS Drugs and Therapeutics (DTC) Drug Review Process Timelines?

Submission/Review Process Timelines

Phase	Estimated Time Range (days)	Comments

1. Submission by requester deemed complete	Not applicable (n/a)	Prescribers and pharmacists within AHS may request changes to the AHS Provincial Drug Formulary and Supplement(s). The requester must complete the applicable 'Drug Formulary Change Request' form.
2. Drug Utilization and Stewardship (DUS) review completed <ul style="list-style-type: none"> Literature search and selection completed Appraisal of data completed Report completed Internal review 	30 – 120 days	<p>The review will be done internally within 45 days, once we have all the relevant information for the review.</p> <p>Progression to the next phase will be dependent on a variety of factors including but not limited to completion of pending reviews by the Canada Drug Agency (CDA), Alberta Health Expert Committee on Drug Evaluation and Therapeutics (ECDET).</p>
3. Circulation of report to stakeholders for review and feedback. Collation of feedback.	0 – 45 days	
4. Subcommittee review	0 – 90 days	Subcommittee review as applicable. Meetings are held 4 to 6 times a year.
5. Report tabled at DTC meeting. Recommendation made or DTC sends back to DUS for further information/clarification	45 – 60 days	Depending on the timing between Subcommittee review (if applicable) and DTC meeting, time to DTC meeting will vary. If DTC requests further information or clarification, the report returns to step 2.
6. Approval of DTC recommendations <ul style="list-style-type: none"> Minutes approval Executive approval 	15 to 90 days	DTC meeting minutes are completed and sent for member review, and then DTC recommendations are forwarded to AHS Executive for approval. AHS Executive may approve recommendations, reject recommendations, or ask for further information or clarification. If further information/clarification is required the review may return to steps 2-5.

Phase	Estimated Time Range (days)	Comments
7. Final recommendation sent via DTC Update newsletter to AHS clinicians. Requestor notified of decision by letter from DTC Chair.	20 -30 days	
Estimated average time per request once Phase 1 is completed.	About 6 months	Time is dependent on all factors noted above and will vary between reviews.

Who do we contact for further info?

➤ *General Information:*

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➤ *Contract Inquiries:*

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