Alberta Health Services

PROCEDURE

TITLE
PROVINCIAL FORMULARY STATUS

SCOPE Provincial	**DOCUMENT #** HCS-25-01
APPROVAL AUTHORITY Clinical Operations Executive Committee	**INITIAL EFFECTIVE DATE** March 9, 2020
SPONSOR Vice President, CancerControl Alberta and Clinical Support Services	**REVISION EFFECTIVE DATE** Not applicable
PARENT DOCUMENT TITLE, TYPE AND NUMBER Provincial Drug Formulary System Policy (#HCS-25)	**SCHEDULED REVIEW DATE** March 9, 2023

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To outline and provide direction on the formulary statuses pertaining to the Alberta Health Services (AHS) Provincial Drug Formulary System (hereafter referred to as “Formulary”).

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Points of Emphasis

1.1 **Authorized prescribers** shall order drugs in accordance with the AHS Formulary and AHS *Provincial Drug Formulary System* Policy.

1.2 Where possible, the Formulary shall align with the *Alberta Health Drug Benefit List*, AHS *Outpatient Cancer Drug Benefit Program List*, and the Alberta Health Specialized High Cost Drug Program.

a) Drugs on any of the above lists or drug coverage programs are not automatically listed on the Formulary.

b) The AHS Drugs and Therapeutics Committee (DTC) shall review and approve all drugs for inclusion on the Formulary and determination of formulary status.

1.3 The formulary status refers to special categories and instructions (see Appendix A: *Formulary Status Abbreviations and Definitions*). Each formulary status code may be used individually and/or in combination to describe a medication's formulary status.

2. Formulary Drugs ('F')

2.1 Drugs with a formulary status of 'F' are approved for use in AHS. Formulary drugs are stocked in AHS pharmacies (contingent on the patient population being served) or are available upon request.

3. Usage Guidelines ('G')

3.1 Formulary usage guidelines ('G' on the Formulary) are established for drugs that the DTC determines additional information will assist and guide clinical decision-making. Guidelines are developed in order to:

a) provide direction for appropriate medication use, which may also be utilized for future evaluation initiatives on medication use;

b) encourage the appropriate use of a medication in accordance with current medical and scientific evidence; and

c) serve as an educational tool.

3.2 Compliance with formulary usage guidelines is encouraged but not required.

4. Restricted Formulary Drugs ('R')

4.1 Drugs are classified as restricted ('R' on the Formulary) when there is potential for the medication to:

a) be used outside of Health Canada or AHS approved indications and there is an absence of literature evidence to support that use;

b) cause clinically significant harm to the patient; and/or

c) result in significant expenditures for AHS.

4.2 Restricted formulary drugs shall only be prescribed when one or more of the following conditions (preferably Sections 4.2a) or 4.2b) below) are met:

a) specified indication(s) or clinical criteria;

b) specified patient monitoring requirement(s);

c) designated physician(s)/specialty or health care professional(s);

d) designated AHS facilities; and

e) compliance with restriction criteria of other formularies or drug coverage programs (e.g., *Alberta Health Drug Benefit List*).

4.3 Compliance with formulary restrictions is required. For use outside of the approved restrictions, the AHS non-formulary processes shall be followed.

5. Therapeutic Interchanges ('TI')

5.1 Therapeutic interchanges ('TI' on the Formulary) are an authorized exchange of **therapeutic alternatives** in accordance with previously established and approved written guidelines within a formulary system. TIs are categorized according to the complexity of patient information and assessment required to implement the TI (see Appendix B: *Therapeutic Interchange (TI) Complexity Levels*).

a) In AHS, TIs are vetted through the DTC and approved by AHS for use in AHS facilities.

5.2 The goals of TIs are to:

a) promote optimal (clinical and economic) medication therapy;

b) promote patient safety through product standardization to decrease chance of errors;

c) clarify medication orders in a timely manner;

d) assist with dosage and/or interval adjustments based on age, weight, or organ function;

e) encourage **IV to PO conversion** where appropriate; and

f) decrease wastage (e.g., dose rounding).

5.3 TIs may be implemented by a Pharmacist without consultation with the original authorized prescriber.

a) The applied TI must be documented in the patient's **health record**.

5.4 In situations where the authorized prescriber does not want the TI to be implemented, the authorized prescriber shall enter an order (e.g., "Do Not Substitute [drug name X]") in the patient's health record after the original medication order. The non-formulary processes will be applied to the medication order.

6. Non-Formulary Drugs ('NF')

6.1 Non-formulary drugs ('NF' on the Formulary) are drugs that have been excluded from the Formulary based on the following rationale:

a) lack of evidence of the medication's effectiveness;

b) safety concerns about the medication;

c) recommendation of "do not list" by the Common Drug Review;

d) lack of cost effectiveness; and/or

e) a therapeutic alternative is on the Formulary (may include a therapeutic interchange).

6.2 Drugs that have not been evaluated for addition to the Formulary will not appear in the Formulary, but are considered to be non-formulary.

6.3 Extemporaneous compounded preparations (including purchased products compounded by third-party compounding services) shall not be listed on the Formulary unless they are associated with criteria of use (restriction, guideline, or TI). This includes ingredients used for compounding that would not be dispensed in its original format (e.g., camphor crystals).

6.4 For more information on handling of non-formulary drugs, refer to the AHS Low-Cost Non-Formulary Process.

7. Do Not Provide ('DNP') – General Statements

7.1 The 'DNP' formulary status indicates a medication that will not be stocked or provided by Pharmacy Services.

7.2 If a DNP medication is ordered, the Pharmacist shall contact the authorized prescriber to discuss formulary alternatives.

7.3 If the authorized prescriber wants the patient to receive a DNP medication while in hospital, the patient must bring their own supply (refer to the AHS *Management of Patient's Own Medications* Policy and procedures).

7.4 The process to appeal a DNP formulary status is outlined in the DTC's Resubmission and Appeal Process.

8. Not Reviewed Do Not Provide Drugs ('NRDNP')

8.1 All new drugs and new dosage forms of existing drugs that receive Health Canada's Notice of Compliance (NOC) and are marketed in Canada shall be assigned an 'NRDNP' formulary status. NRDNP drugs will not be stocked or provided by Pharmacy Services.

a) The 'NRDNP' formulary status shall remain in effect until the medication has been reviewed by the DTC.

b) The 'NRDNP' formulary status does not apply to Health Canada's Special Access Programme (SAP) drugs.

8.2 Requests for addition to the Formulary may be submitted for NRDNP drugs.

a) Hospital-only NRDNP drugs shall be automatically reviewed for addition to the Formulary with a prioritized timeline of three (3) to six (6) months.

(i) If the medication has the potential to be life-saving, the review shall be prioritized on a more urgent timeline.

(ii) If a decision on a medication needs to be completed on a more urgent timeline, the medication shall be prioritized for review using the DTC's approval processes.

b) NRDNP drugs that can be used outside of hospital shall be reviewed for addition to the Formulary once the *Alberta Health Drug Benefit List* recommendations are finalized, when applicable.

(i) The formulary review will be initiated by the Pharmacy Therapeutics Team upon receipt of an AHS *Formulary Addition Request* Form or at the discretion of the DTC.

c) The DTC will be notified of all new drugs assigned an 'NRDNP' formulary status at the next DTC meeting.

8.3 Formulary Status Objection Process for NRDNP drugs

a) If an authorized prescriber requests access to a medication assigned an 'NRDNP' formulary status, an explanation of the 'NRDNP' status including review timelines shall be provided to the prescriber.

b) If further escalation of objection is requested by the authorized prescriber, they should be referred to the Manager of Drug Utilization, Information and Stewardship (DUIS), Pharmacy Services.

c) The AHS Short-term Exceptional Drug Therapy (STEDT) Process may be applied for drugs exceeding $1,500 per patient course of therapy.

9. Non-Formulary Do Not Provide Drugs ('NFDNP')

9.1 Drugs with an 'NFDNP' formulary status have been reviewed by the DTC and excluded from the Formulary. They will not be stocked or provided by Pharmacy Services (including through the Non-Formulary Process) because they:

a) have no known/perceived clinical role in the treatment of patients;

b) are associated with potential/significant safety risk(s) which outweigh the known/perceived benefit(s); and/or

c) have a similar clinical/safety profile to other available medication and non-medication therapies but are associated with significant, unjustifiable, incremental costs.

9.2 The formulary review including rationale for 'NFDNP' status and suggested formulary alternatives shall be posted in the formulary record for the product on the Formulary databases.

9.3 Formulary Status Objection Process for NFDNP Drugs

a) If an authorized prescriber wants access to a specific medication assigned an 'NFDNP' formulary status, the prescriber should be provided with the DTC-approved formulary evaluation outlining the rationale for the recommendation.

b) If further escalation of objection is requested by the authorized prescriber, the medication-specific decision may be appealed via the DTC's Resubmission and Appeal Process.

10. Special Access Programme ('SAP')

10.1 SAP drugs are therapeutic agents including pharmaceuticals, biologics, and radio-pharmaceutical products that are not approved for sale in Canada but may be available through Health Canada's Special Access Programme. SAP drugs may be reviewed for Formulary upon request and subject to the same review principles and decision status as other drugs.

11. Unfunded Drugs

11.1 An unfunded drug is any drug provided by the patient for administration in an AHS ambulatory setting that is not routinely administered in AHS, and has not been previously approved for administration by AHS. Requests to administer unfunded drugs are made through the Request to Administer Unfunded Drugs in AHS Process. Consideration shall be given through this process as to whether AHS will administer the medication to ensure a consistent approach across AHS.

DEFINITIONS

Authorized prescriber means a health care professional who is permitted by federal and provincial legislation, their regulatory college, Alberta Health Services, and practice setting (where applicable) to prescribe medications.

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

IV to PO conversion means a parenteral agent is changed to an oral or enteral agent in the acute stages of an illness or when clinically feasible for a patient. The oral or enteral agent used should provide excellent bioavailability and/or equivalent or near equivalent spectrum of activity.

Therapeutic alternatives are drug products with different chemical structures but of the same pharmacologic or therapeutic class and that usually have similar therapeutic effects when administered to patients in therapeutically equivalent doses. In some instances, the therapeutic

alternatives may be for a different dosage form, route, or dosage regimen of the same drug product.

REFERENCES

- Appendix A: *Formulary Status Abbreviations and Definitions*
- Appendix B: *Therapeutic Interchange (TI) Complexity Levels*
- Alberta Health Services Governance Documents:
  - *Management of Patient's Own Medications* Policy and procedures (#PS-98)
  - *Provincial Drug Formulary System* Policy (#HCS-25)
- Alberta Health Services Forms:
  - *Formulary Addition Request* Form (#04976)
- Alberta Health Services Resources:
  - *Outpatient Cancer Drug Benefit Program List*
- Non-Alberta Health Services Documents:
  - *Alberta Health Drug Benefit List*

VERSION HISTORY

Date	Action Taken
Click here to enter a date	Optional: Choose an item
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APPENDIX A

Formulary Status Abbreviations and Definitions

Note: Each of the formulary status codes outlined in the table below can be used individually and/or in combination to describe a product's formulary status on the AHS Provincial Drug Formulary and Supplements.

Abbreviation	Description	Comments
C	Correctional Facilities	Indicates that the formulary status of a drug on the AHS Correctional Facilities Drug Formulary Supplement differs from its status on the AHS Provincial Drug Formulary. Exception: Formulary status code "DC": Manufacturer Discontinued.
DC	Manufacturer discontinued	Product no longer available on the Canadian market.
DEF	Deferred to Provincial DTC for decision	If the initial provincial formulary consolidation recommendation had major disagreement from former regions' P&T Committees, these items were deferred to the Provincial DTC for decision.
DNP	Do Not Provide	Will not be stocked or supplied by AHS Pharmacy Departments.
F	Formulary	Listed for use on formulary or Supplement(s).
G	Usage guidelines	Listed with guidelines for use.
NF	Non-Formulary	Reviewed and excluded from the formulary or Supplement(s).
NPP	Not a pharmacy product	This product is not supplied by pharmacy departments within AHS but may be available from other departments (e.g., Diagnostic Imaging or "Stores" [Contracting, Procurement Supply Management]).
NR	Not Reviewed	
PEND	Pending	Formulary status is recommended but pending provincial review or feedback, other policy decision, or other factors.
R	Restricted	Listed with criteria/restrictions.
SAP	Health Canada Special Access Programme	These products are not marketed for sale in Canada but may be available and require approval for use through the Health Canada Special Access Programme.
TI	Therapeutic Interchange	
UR	Under review	Currently being reviewed for formulary by Provincial DTC.

APPENDIX B

Therapeutic Interchange (TI) Complexity Levels

TIs are classified into three levels depending on:

- Type/amount of patient information required
- Degree of pharmacist assessment and monitoring required

Level 1 – Lowest Complexity (e.g., topical corticosteroid TI based on potency class):

- No patient specific information required
- Minimal pharmacist assessment or monitoring required

Action: Pharmacist may implement interchange from dispensary.

Example:

Original Order	Supplied Order
Nizatidine 150 mg po BID	Ranitidine 150 mg po BID
Senokot S (docusate sodium 50 mg and sennosides 8.6 mg) - any dose, any frequency	Sennosides 8.6 mg tablet, same dose, same frequency

Level 2 – Mid Complexity (e.g., renal dosage adjustment):

- Additional patient specific information required e.g., renal or hepatic function
- Additional pharmacist assessment required e.g., determine whether patient has condition that would be an exception to the TI

Action: Interchange may be implemented by pharmacist in the dispensary if required information is available (refer to clinical pharmacist if required information is missing).

Example:

Original Order	Supplied Order
Cefoxitin 1-2 g in O&G surgical prophylaxis in adult patients	Cefazolin 2 g IV
Meropenem 1-2 g IV q6-8h in adults	Meropenem 500 mg IV q6h in adults‡ EXCEPT in cystic fibrosis, central nervous system infections, or ophthalmologic infections. For these infections, contact prescriber to suggest dose of 2g IV q8h.

Level 3 – Highest Complexity (e.g., IV to PO conversion):

- Detailed patient specific information required
- Extensive pharmacist assessment or monitoring required, e.g., resolution of drug–drug interactions

Action: Medication orders should be deferred to the clinical pharmacist for investigation, implementation, and follow up.

Example:

Original Order	Supplied Order
Ciprofloxacin 200 mg IV Q12H where patient is on enteral feeds or oral/NG drugs	Ciprofloxacin 500 mg PO (or via tube) Q12H+* + For patients whose Clcr is calculated to be < 30 mL/min (0.5 mL/s), the dosing interval of the ciprofloxacin will be changed to daily. *Tube feeds should be stopped for 1 hour prior to and 2 hours following dose. Flush feeding tube with 30mL NS prior to & following each dose. Where tube feeds cannot be discontinued, recommend continue with IV ciprofloxacin. NOTE: Therapeutic interchange will NOT occur until pharmacist has resolved potential drug interaction issues, if they exist.