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SUBJECT/TITLE FPP-05 Special Access Program (SAP) - Drug Use Process	ORIGINAL DATE: REVISION DATES:	14-12-2006 25-01-2007 28-03-2013 16-06-2026

PURPOSE

The purpose is to provide guidance to contracted Type A pharmacy providers and Type A Continuing Care Homes (CCHs) on managing a request for a drug accessed through the Health Canada Special Access Program (SAP) for drugs, and to provide monitoring parameters for such requests.

DEFINITION

Health Canada describes the Special Access Program (SAP) for drugs as the following, *"Through SAP, health care professionals may request access to drugs that are not currently authorized for sale in Canada to treat patients with serious or life-threatening conditions. Access to these drugs is only considered when conventional therapies have failed, are unsuitable or are unavailable."*

A SAP authorization allows a manufacturer to sell a drug that has not been authorized for sale in Canada. Drugs considered for release under SAP include pharmaceutical, biologic and radiopharmaceutical products." ([Health Canada's special access programs: Overview - Canada.ca](http://HealthCanada.ca/special-access-programs/Overview-Canada.ca))

Under Information for Patients, Health Canada further states *"An authorization under the SAP is not the same as full market approval. Drugs and medical devices approved under the SAP have not gone through our full review for safety, efficacy/effectiveness, or quality"*. ([Health Canada's special access programs: Information for patients - Canada.ca](http://HealthCanada.ca/special-access-programs/Information-for-patients-Canada.ca))

SAP DRUG USE PROCESS

For the purposes of Calgary Type A CCHs, any drug that is obtained from SAP is classified as a Non-Formulary (NF) medication.

This process assumes that the SAP drug is initiated by a specialist physician or provided for continuation of therapy upon admission. It assumes that Health Canada has approved the SAP request and the drug manufacturer agrees to comply with the request. All the terms and conditions of the SAP are the responsibility of the SAP drug requestor/prescriber and the resident's most responsible medical practitioner (MRSP).

It presumes that no formulary or Canadian commercially available drug product can be used in place of the SAP drug.

An Integrated Supportive & Facility Living (ISFL) pharmacist may be involved at any point in the process.

1. Agreement on the need for SAP drug therapy must be reached by the resident's MRSP and the pharmacy provider. **Note:** If consensus is not achieved and the process does not proceed to the next steps, the drug will not be funded.
2. Informed consent must be obtained and documented for use of the SAP drug product from the resident or their agent in the Type A CCH setting.
3. The process for NF Drug Funding requests must be followed. Refer to *FPP-03 – Non-Formulary Drug Funding Requests*. The clinical pharmacist completes the *Non-Formulary Drug Use Request Form* and submits to ISFL Drug Management via email to cc.drugmanagement@albertahealthservices.ca or fax to



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(403) 943-0232 for review and a decision. Alternatively, the NF request may be submitted by the SAP prescriber or the MRSP.

4. SAP drug products are typically sourced through an AHS contracted outpatient pharmacy. As per SAP program restrictions, sales of SAP products are restricted to a location identified in the SAP application and confirmed in the approval Letter of Authorization. Any changes would require a transfer via the SAP program channels.
5. SAP refill requests and prescription renewals must be sent directly to the dispensing pharmacy; the Type A pharmacy provider and clinical pharmacist may assist the Type A home and MRSP in this process.

MONITORING

Ongoing monitoring of SAP drug use shall be the joint responsibility of the Type A CCH care team as well as the medical specialist who was responsible for initiating SAP therapy.

SAP drug utilization will be monitored and reviewed by the ISFL Pharmacist and the Calgary Type A CCH Pharmacy and Therapeutics Committee. In the event the Chair(s) or Committee determines that an occurrence of SAP drug use cannot be supported with a rational clinical case, the drug will not be funded and the clinical pharmacist will be notified.

REFERENCES

Health Canada. (n.d.). Overview: Special access programs. Retrieved November 19, 2025, from [Canada.ca](https://www.canada.ca)