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PURPOSE

To manage requests for and monitor utilization of medications through the Health Canada Special Access Program.

DEFINITION

The Health Canada document "*Special Access Programme (SAP) - Instructions for Making a Special Access Request*" states the following:

"The Health Canada Special Access Program (SAP) provides access to nonmarketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. Drugs considered for release by the SAP include pharmaceutical, biologic, and radio-pharmaceutical products not approved for sale in Canada.

Any medication that is obtained from the SAP is classified as a Non-Formulary medication (see FPP-01).

The Health Canada document "*Special Access Programme (SAP) - Instructions for Making a Special Access Request*" also states:

"SAP authorization does not constitute an opinion or statement that a drug is safe, efficacious or of high quality. The SAP does not conduct a comprehensive evaluation to ensure the validity of drug information or attestations of the manufacturer respecting safety, efficacy and quality. These are important factors for practitioners to consider when recommending the use of a drug and in making an appropriate risk/benefit decision in the best interests of the patient."

POLICY:

1. All medications covered under the Special Access Program (SAP) and required by a Long Term Care must be supplied through the AHS contracted outpatient pharmacy provider. As per SAP program restrictions, sales of SAP products are restricted to physician clinics or to hospitals; sales to retail pharmacies are not permitted.
2. The SAP considers requests and authorizes the drug manufacturer to release medication to the outpatient pharmacy. The manufacturer has the right to refuse to comply with the request.
3. SAP refills and prescription renewals must be sent directly to the hospital outpatient pharmacy; the pharmacy service provider or site clinical pharmacist may assist the facility and prescriber in this process.

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4. SAP drug use is documented on the Non-Formulary Drug Use Request and/or Request for Addition to/Deletion from Formulary FPP-01 Form and reported to the Long Term Care P&T Committee.

SPECIAL ACCESS PROGRAM DRUG USE PROCESS:

This process assumes that SAP medication is initiated by a specialist physician or provided for continuation of therapy from pre-admission. It is also assumed that no formulary or commercially available drug product can be used in place of the SAP product.

The Regional Pharmacy Consultant may be involved at any point in the process.

1. The Most-Responsible Physician, Facility Site Leader Medical, and the pharmacy services provider must all be in agreement of therapy.
2. Informed consent must be obtained and documented for use of the SAP drug product from the client or family.
3. Drug provision is documented on Part A of the Non-Formulary Drug Use Request FPP-01 Form and submitted by the Pharmacy Provider to AHS pharmacists via email to cc.drugmanagement@albertahealthservices.ca, OR by Physician via fax to 943-0232. The Pharmacy Provider must ensure completion of the "Approved by" section at the bottom of Part A to indicate resolution.
4. SAP products must be sourced through an AHS Outpatient Pharmacy. The pharmacy services provider shall be responsible for acquisition of the drug product and re-packaging into compliance packaging as appropriate for the client's needs.
5. Ongoing monitoring of the SAP therapy shall be the joint responsibility of the LTC care team as well as the attending specialist medical service who was responsible for initiating SAP therapy.

Note: In situations where SAP drug use is not agreed upon and the process not continued through step 9 above, the drug will not be funded.

MONITORING

SAP drug utilization will be monitored and reviewed by the Regional Pharmacy Consultant and/or the Long Term Care P&T Committee, and reported to administration.

In the event the Chair and/or Committee determine that an occurrence of SAP drug use is not necessary and a rational clinical case to support the use of a non-formulary drug can not be made; the drug will not be funded, and the Pharmacy Provider will be notified.

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References:

"Special Access Programme (SAP) - Instructions for Making a Special Access Request", available at;
http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogués/sapq2_pasq2_e.html

"Special Access Request Form", available at;
http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogués/sapf1_pasf1_html_e.html

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