Drug Formulary

User's Guide

Sask cancer AGENCY

The Saskatchewan Cancer Agency (SCA) Drug Formulary provides a listing of the drugs funded for the treatment of cancer conditions in Saskatchewan patients registered with the SCA. The Ministry of Health provides funding to the Cancer Agency to prepare, dispense and administer cancer drug treatments without cost to patients.

Oversight and management of the SCA Drug Formulary is the responsibility of the SCA through its Pharmacy and Therapeutics (P&T) Committee. Special funding approval for a drug or indication not listed on the formulary may be considered in exceptional clinical circumstances through the Case-by-Case Review Program (CBCRP).

The SCA Drug Formulary is distinct from the drug formulary of the Saskatchewan Prescription Drug Plan (SPDP). There are a few supportive care drugs designated for coverage within the Cancer Agency and listed on the SCA Drug Formulary, but many supportive drugs used by cancer patients (e.g., anti-infectives, anti-thrombotic agents, medications for pain management, etc.) are not provided or funded by the Cancer Agency. In general, these drugs are listed on the SPDP drug formulary and follow prescription drug coverage policies of the SPDP.

This User's Guide is designed to assist in understanding the SCA's drug coverage program and interpretation of the information contained within the Drug Formulary.

I. Authorized Physicians

Medical oncologists, radiation oncologists, gynecology oncologists and hematologists employed by the Cancer Agency are authorized to prescribe formulary drugs for registered cancer patients, hereafter referred to as authorized Cancer Agency physicians.

Physicians employed by the Cancer Agency as clinical associates and nurse practitioners may be given authority to prescribe specific formulary drugs for cancer patients by their supervising oncologist or hematologist. Clinical associates and nurse practitioners are limited to prescribing drugs that are a continuation of treatment initiated by an authorized Cancer Agency physician.

Non-Cancer Agency physicians practicing in specific medical specialties, hereafter referred to as associated prescribing physicians, may be granted the authority to prescribe certain formulary drugs for specific indications to registered cancer patients. The majority of these include:

- Pediatric oncologists for the treatment of children's cancers
- Urologists for the treatment of prostate cancer and superficial bladder cancer
- Other specialists, such as dermatologists for skin-directed cancer treatments, ophthalmologists for the topical treatment of eyelid, conjunctival and corneal neoplasms, interventional radiologists for trans-arterial chemo-embolization, oncologic surgeons for intralesional treatment of in-transit melanoma and nuclear medicine radiologists for radiopharmaceuticals

Only authorized Cancer Agency physicians and associated prescribing physicians may initiate cancer treatment with formulary drugs for Cancer Agency funding. The indications for drug funding are applicable for registered cancer patients in both hospital (except as noted in section VI) and outpatient treatment settings.

Family physicians may prescribe continuation of specific cancer medications (e.g., adjuvant endocrine therapies for breast cancer) through the Cancer Centre pharmacies when directed by the treating cancer physician at the time a patient is discharged from the Cancer Centre for follow-up and continuation of cancer drug treatment.

II. Saskatchewan Cancer Agency Pharmacy and Therapeutics Committee

The Saskatchewan Cancer Agency Pharmacy and Therapeutics (P&T) Committee, with membership from medical, pharmacy, nursing and senior leadership, governs all policies of drug use within the Cancer Agency and is responsible for making recommendations for listing of all cancer drug programs on the Cancer Agency Drug Formulary. The P&T Committee also oversees the CBCRP.

The P&T Committee aligns with the Canadian Association of Drugs and Technology in Health (CADTH) drug reimbursement review program and accepts the recommendations for new oncology drugs and indications. Drugs given a conditional recommendation require completion of price negotiations between the pan-Canadian

Pharmaceutical Alliance (pCPA) and the Manufacturer before they will be considered for Cancer Agency funding.

In general, the eligibility requirements for drugs listed on the Cancer Agency Drug Formulary represent the approved standards of care within the systemic treatment guidelines of the Cancer Agency.

III. Formulary Listing and Eligibility Requirements

Formulary approved drugs are listed alphabetically by their generic drug name. The tradename may be listed for some combination products or special formulations. The formulary does not fund all available manufacturers of a drug product where multiple products exist for a drug. The drug program of the Cancer Agency is similar to a hospital and provides only one drug product brand at any one time according to drug contracting processes. The drug strengths listed may not be comprehensive of all strengths available, but represent those used in the treatment of cancer conditions**.** The Drug Formulary does not list drugs which are not funded (i.e., non-formulary drugs).

Some formulary drugs have a special status designation within the Cancer Agency called STEP (SCA Treatment Evaluation Program) which is an internal registration or approval process to support the ability of the P&T Committee to monitor drug program use when required. The STEP process does not affect the formulary funding of the drug. Although Health Canada approval of a drug is required for listing on the SCA Drug Formulary, there are a few exceptions of drugs not approved by Health Canada listed on the formulary considered critically necessary and available through Health Canada's Special Access Programme (SAP).

Many drugs are listed with eligibility requirements for funding, which may include criteria for use in specific cancers, specific treatment settings, in combination with other drugs and/or in patients who meet various eligibility factors. In general, eligibility requirements follow the clinical trial evidence for use of the drug and align nationally with the CADTH recommendations for reimbursement. Formulary eligibility requirements are not inclusive of the many patient factors (e.g., co-morbidities, organ function) important for safe use of cancer drug therapy. Although not specified for each formulary drug, patients eligible for cancer drug therapies should have a good performance status which is interpreted as a performance status of 0, 1 or 2 on the Eastern Cooperative Oncology Group (ECOG) Scale of Performance Status. Some formulary drugs have eligibility criteria that specifically restricts use only in patients who have an ECOG performance status of 0 or 1.

The formulary does not include complete treatment protocol information for use of cancer drugs, such as the drug regimen (single agent or drug combinations), dosing, monitoring requirements and duration of therapy, unless specific to funding eligibility criteria. Eligibility criteria for some cancer drugs have defined treatment durations (e.g., number of approved cycles or time limits). When not specified in the formulary eligibility for each drug, the standard treatment duration for cancer drugs given on a continuous basis for advanced cancers is until disease progression or unacceptable toxicity.

Some cancer drugs have eligibility criteria restricting use in a particular line of therapy. Although not specifically defined in the formulary listing, if there are choices of more than one drug within a line of treatment, switching to an alternate drug with eligibility in the same line of treatment is funded in the situation of intolerance to the first chosen drug provided there is no evidence of disease progression. The formulary eligibility criteria may also define restrictions on treatment sequencing, identifying which drugs could or could not have been given prior to a funded cancer drug or which drugs can or cannot be given after use of a funded cancer drug.

Drugs which have been available for a long time and/or are commonly used across multiple cancers may not have any eligibility restrictions for their use. Use of a drug in situations that do not meet eligibility criteria is considered non-formulary and is not funded.

IV. Case-by-Case Review Program (CBCRP)

An authorized Cancer Agency physician or associate prescribing physician may request funding for use of a drug or indication which is outside of the approved eligibility criteria or non-formulary. In these situations, the request must be documented on the Case-by-Case Review Program Application Form and submitted through the designated process for review and consideration. Applications must include the clinical reason for the request, scientific evidence for benefit, the patient's clinical history and prior cancer treatment(s), reasonable

therapeutic alternatives, and estimated total treatment cost. In addition, an annual provincial estimate of the number of similar cases may be required.

Drugs and/or clinical indications which represent major changes in the funded standard of care and/or are currently in the CADTH review or pCPA negotiation process cannot be requested through CBCRP. A physician or disease site group may make a formal submission to the P&T Committee to review a new drug program for consideration of funding and Drug Formulary listing provided the new drug or indication will not be reviewed by CADTH.

V. Cancer Centre Pharmacies

Provision of cancer drugs on an outpatient basis according to the list of drugs and approved funding indications on the Drug Formulary is the responsibility of the pharmacies located in the Allan Blair Cancer Centre and the Saskatoon Cancer Centre (see below). This includes the dispensing of cancer drugs for administration in the outpatient chemotherapy treatment units of the tertiary cancer centres, to cancer patients for administration at home and to the Community Oncology Program of Saskatchewan (COPS) centres.

All outpatient prescriptions for formulary cancer drugs from authorized prescribers must be dispensed by a Cancer Centre Pharmacy. The Cancer Agency does not reimburse community (retail) pharmacies for the dispensing of cancer formulary drugs. Saskatchewan patients who purchase their cancer formulary drugs from a community (retail) pharmacy will only be reimbursed at the formulary drug cost of the Cancer Agency, provided the indication for use meets funding eligibility criteria.

Allan Blair Cancer Centre Pharmacy
4101 Dewdney Avenue
Regina SK S4T 7T1
Tel: (306) 766-2816 Fax: (306) 766-2183

Saskatoon Cancer Centre Pharmacy
20 Campus Drive
Saskatoon SK S7N 4H4
Tel: (306) 655-2680 Fax: (306) 655-1035

VI. Cancer Drugs in the Hospital

Formulary-approved injectable cancer drug treatments for patients in the hospital are funded, prepared and provided from the Cancer Centre pharmacies. Formulary-approved oral cancer drug treatments for patients in the hospital are also provided by the Cancer Centre pharmacies. Patients admitted to hospital who have been taking an oral cancer drug treatment at home previously provided by the Cancer Centre pharmacies which will be continued during hospital admission are encouraged to bring their drug supply into the hospital. Supportive drug therapies listed on the Cancer Drug Formulary (e.g., ondansetron, pamidronate, zoledronic acid) are provided by the Cancer Centre pharmacies only for outpatient use and are not provided or funded for hospitalized patients

Injectable cancer drug treatments given in designated community hospitals outside Saskatoon and Regina are provided by the Cancer Centre pharmacies within the Community Oncology Program of Saskatchewan and are administered on an outpatient basis in these community sites.

VII. Stem Cell Transplant and Cellular Therapy Program (SCTCTP)

Drug treatment protocols developed within the provincial Stem Cell Transplant and Cellular Therapy Program (SCTCTP) must be approved for funding by the P&T Committee. Formulary drugs with restricted criteria must list the transplant indications approved for use within the SCTCTP.

VIII. Pediatric Oncology

Childhood cancers are often treated according to study protocols from the Children's Oncology Group (COG). It is the responsibility of Saskatchewan Health Authority pediatric oncologists to submit requests to the Cancer Agency P&T Committee for COG protocols which require use of cancer treatment drugs not currently on the formulary or outside of approved formulary eligibility criteria before the COG protocols can be made available. The P&T Committee will review requests in regard to potential impact on drug use and funding and only if decisions are made to provide formulary drug approval can the COG study be opened for patient enrollment.

If it is desired to treat a child's cancer by following a COG protocol (i.e., without study enrollment) that includes use of a non-formulary drug or indication, a request must be made by completing the CBCRP application form and submitting through the designated process. This request is required even if Cancer Agency funding had been approved for the non-formulary drug or indication for patients actively enrolled on the study and in situations where the non-formulary drug would have been provided free of charge for active study participants

IX. Clinical Trials

Commercial drugs used within clinical trials may be outside the listed indications on the Drug Formulary. Prior to initiation, all clinical trials require a review by the P&T Committee regarding impact on drug use and cost, both for the study drug regimen and, if applicable, the 'standard' comparator regimen. The review will also include the impact on drug use and cost of supportive drug treatments expected to be funded by the Cancer Agency and how clinical trial participation affects subsequent treatments following completion of the study or at the time of disease progression. If the outcome of the review identifies excessive drug costs, the clinical trial may not be supported unless outside funding is acquired.

X. Out-of-Province Drug Benefits

Reimbursement for the cost of 'take home' drugs provided to Saskatchewan cancer patients receiving cancer care in another province or territory will follow the Drug Formulary eligibility listings. Use of drugs not on the Drug Formulary or for a non-approved indication will not be funded by the Cancer Agency and will not be reimbursed, nor provided to a cancer treatment facility outside of Saskatchewan. In order for reimbursement of 'take home' drug costs to an out-of-province health organization or to the patient, the Cancer Agency requires patient registration and current clinical progress information regarding the treatment plan and outcome. Depending on the situation, patients may not be reimbursed full drug costs incurred if the 'take home' drug was provided through an out-of-province retail pharmacy. Cancer drug treatments administered by a health organization (hospital or cancer treatment centre) are generally billed to the Province of Saskatchewan through interprovincial billing agreements.

XI. Out-of-Country Elective Drug Benefits

Coverage for out-of-country cancer drug treatment is only considered in exceptional circumstances and under certain conditions, and physicians recommending and seeking out-of-country drug treatment on behalf of their patients must request and receive prior approval from the Cancer Agency and Medical Services Branch of the Ministry of Health prior to referring their patients for drug treatment outside of Canada.

Patients who elect to seek drug treatment or alternative opinions outside of Canada on their own, without an approved physician referral, will not be eligible for reimbursement of out-of-pocket drug expenses. Cancer drugs recommended by specialists outside of Canada can only be considered if the recommended medications are currently funded by the Cancer Agency according to the criteria listed in the Drug Formulary and prescribed by an authorized Cancer Agency physician.

Further information on out-of-country medical coverage can be found at: www.health.gov.sk.ca/out-of-province

XII. Premedications/Wardstock Items

Miscellaneous drug products administered to patients within the Allan Blair Cancer Centre and Saskatoon Cancer Centre to support cancer drug treatments or medical procedures are not listed within the Drug Formulary, but are provided at no cost to the patient.

XIII. Supply of Cancer Drugs for Self-Administration

In general, patients are provided with a supply of cancer drugs for self-administration (e.g., oral drugs) that is limited to what is safe and appropriate, taking into account the type of medication, requirements for standard monitoring and follow-up, the type of cancer being treated, the general status and treatment history of the patient and the cost of the drug.

For patients who will be absent from the province of Saskatchewan for an extended period of time, and not able to attend regular review and follow-up appointments with their physician during that time, an extended supply of some cancer drugs may be provided according to Cancer Agency policy (http://www.saskcancer.ca/health-professionals-article/request-for-extended-cancer-drug-supplies-policy)

Disclaimer:

The Saskatchewan Cancer Agency Drug Formulary is an **information-only** resource that identifies the funding status and eligibility requirements of cancer treatment drugs and some supportive drugs used to care for cancer patients in Saskatchewan. It is current only as of the date listed on the Drug Formulary, and is not intended to constitute medical advice.