

POLICY

Title: Request for Extended Cancer Drug Supplies

Issue date: 2015/10/01

Revised date: 2023/04/01

Document #: PMY 1408- 1PO

Location: SCA

Policy Statement: 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/Nurse Practitioner (NP) during that time, may ask their physician/NP to apply for a supply of their cancer drugs eligible for provision of extended supplies as listed in APPENDIX A.

It is the responsibility of the prescribing physician/NP to ensure that the patient's medical status and tolerability of the cancer drug are sufficient to safely prescribe the extended drug supply prior to submitting the application form.

Purpose:

1. To provide standards for prescribing, dispensing and funding of extended supplies of cancer drugs from the Saskatchewan Cancer Agency (SCA).
2. To balance the needs of patients for extended supplies of cancer drugs against clinical standards (best practices), patient safety (non-maleficence) and minimizing risk of harm to patients (beneficence).
3. To ensure equitable outcomes for all patients balanced against limited drug resources, while ensuring appropriate access to care (procedural justice).
4. To ensure extended supplies of cancer drugs provided to patients are based on safe medical practices in managing patients receiving cancer drug therapy, taking into account the type of medication, requirements for standard monitoring and follow-up, the type of cancer being treated and the general status and treatment history of the patient.

Application: This policy applies to all personnel employed by the Saskatchewan Cancer Agency who are authorized to prescribe or dispense cancer drugs.

Document Owner: *Director Oncology Pharmacy Services*

Authority: Vice President Care Services
Vice President Medical Services and Senior Medical Officer

Approved by/date: <u> <i>Nenise Budz</i> <u> May 5, 2023 </u> (Insert digital signature here) </u>
Approved by/date: <u> <i>[Signature]</i> </u> (Insert digital signature here)

Version	Author	Approver	Approval Date	Description of Changes
2022/10/26	<i>Director Oncology Pharmacy Services</i>			Addition of Case-by-Case review process Formatting edits

Procedure Summary: SCA Pharmacy and Therapeutics Committee is responsible for determining which cancer drugs with dispensing limits will be eligible for provision of extended supplies to address extended patient absence from Saskatchewan. Its decision will be based on the type of cancer being treated, the way the drug works in the body, the side effects that may occur and the need for close medical monitoring and follow-up. A standardized process for evaluation of exceptional circumstances using a case-by-case review process has been developed for use when required.

1. CANCER DRUG ELIGIBILITY ASSESSMENT

STEP	ACTION:
1.1	<p>A list of cancer drugs taken orally or given by intramuscular/subcutaneous injection along with the maximum duration of extended supply will be reviewed and updated on a regular basis by the SCA Pharmacy and Therapeutics Committee (P&T) - please refer to APPENDIX A.</p> <ul style="list-style-type: none"> - Drugs that require close medical monitoring on a cyclic or monthly basis for safe use will not be approved for extended supply. - Cancer drugs which require intravenous infusion within a treatment centre will not be approved for extended supply. - An appeals process for exceptional circumstances using a case-by-case review process is available – please see <i>Section 4</i> below.

2. PHYSICIAN ASSESSMENT FOR PATIENT ELIGIBILITY AND ORDERING

STEP	ACTION:
2.1	<p>For patients who will be absent from the province for an extended period of time and who have requested supply of a cancer drug eligible for provision of extended supplies as listed in APPENDIX A, it is the responsibility of the prescribing physician/nurse practitioner (NP) to ensure that <u>all the following conditions are met prior to completing the pre-printed orders</u>:</p> <ul style="list-style-type: none"> <input type="checkbox"/> the patient has been receiving the drug for a sufficient length of time to assess treatment response and tolerability; <input type="checkbox"/> the medical condition of the patient is stable; <input type="checkbox"/> a prescription is written for the extended drug quantity not exceeding the approved duration limits approved in APPENDIX A. <i>Requests for an extended drug supply exceeding amounts listed on pre-printed orders must be submitted to Pharmacy at least 10 business days prior to the patients expected date of travel to ensure adequate supply of medication is available;</i> <input type="checkbox"/> the patient is informed of any laboratory and/or other medical investigations that would be necessary for safe drug therapy during their extended absence with the understanding that it will be their responsibility to obtain these investigations during their absence (including paying for the investigations, if applicable) and providing the results to their physician; <input type="checkbox"/> the patient is informed and understands their responsibility of obtaining and paying for injection-related services outside of Saskatchewan for those drug administered by intramuscular or subcutaneous injection, when required; <input type="checkbox"/> the patient is informed that the SCA will not be responsible for replacement of any lost, stolen or damaged drugs and any other expenses incurred outside Saskatchewan for treatment of their cancer; <input type="checkbox"/> the patient’s medical record documentation is completed to indicate the following: <ul style="list-style-type: none"> - the duration of the patient’s absence from the province; - the quantity of extended cancer drug supply prescribed; - assessment that the patient’s medical status and tolerability of the cancer drug are sufficient to safely prescribe the extended drug supply; and - investigations that the patient will be required to obtain during the extended medication period for reasons of safe drug use.

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STEP	ACTION:	
2.2	If the prescribing physician/NP determines that the patient has met the conditions, they can prescribe the extended supply using the appropriate pre-printed orders.	
2.3	Pharmacy staff will review the order and ensure it is included and follows the allowed amount specified in the Eligibility of Drugs for Extended Drug Supply list - APPENDIX A.	
	If	Then
	If the order <u>is not</u> included/exceeds the allowed amount specified in the Eligibility of Drugs for Extended Drug Supply list	Pharmacy staff will notify the physician/NP. The physician/NP may choose to submit a case by case review request – see <i>Section 4</i> below.
	If the order <u>is</u> included/follows the allowed amount specified in the Eligibility of Drugs for Extended Drug Supply list	Pharmacy staff will dispense if inventory is available or request inventory staff to bring in an adequate supply.

3. PATIENT PROCESSES

STEP	ACTION:	
3.1	The patient will obtain their extended drug supply from either the Allan Blair or Saskatoon Cancer Centre Pharmacy.	
3.2	The pharmacist will have the patient sign a Document of Understanding (Extended Drug Supply) - see APPENDIX B - outlining their responsibility with regard to receiving an extended supply of their cancer drug that aligns with the information provided to them by their physician.	
3.3	The Pharmacy staff will provide the patient with a copy of their signed Document of Understanding (Extended Drug Supply) and place the original in the patient's medical record. If the prescription is sent to the patient rather than pick-up, the Pharmacy staff will obtain a verbal consent from the patient with accompanying documentation in Aria MO and send a paper copy of the consent form to the patient with their package (see CSD 110 Patient Consent for Treatment or Procedure).	
	Unique patient situations:	
	If	Then
3.4	If the maximum duration of cancer drug supply is insufficient to meet the patient's extended absence	the patient may opt to do one of the following: <ol style="list-style-type: none"> 1. choose to return to the SCA for medical follow-up and obtain further drug supply; 2. request a letter of referral from their SCA physician/NP to facilitate continuation of their drug therapy by a physician/NP wherever the patient will be located; 3. request their physician/NP submit a request for a case by case review – see <i>Section 4</i> below.
	If the patient remains within Canada	<ul style="list-style-type: none"> - It is the patient's responsibility to confirm drug cost coverage in the visiting province. - Intravenous cancer drug therapy may or may not be provided free of charge to the patient, depending on the cost of the drug and what drugs are publicly funded, as cancer drug formularies vary among provinces. - Generally, patients are responsible for the cost of oral cancer and take home drugs outside of Saskatchewan.

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STEP	ACTION:	
	If	Then
	If cancer drugs are obtained by the patient outside the province of Saskatchewan,	<ul style="list-style-type: none"> - The patient will be responsible for paying for the cost of the drugs upfront and then submit a claim reimbursement from SCA upon return to Saskatchewan. - The SCA will reimburse drugs only which are already approved for funding according to the SCA Drug Formulary, and only to a maximum of the SCA drug cost. - The SCA will not reimburse any drug cost claims if the purchase of drugs was required to replace damaged or lost drugs previously provided by the Cancer Agency. - The patient will be solely responsible for any other medical or treatment-related costs. - If needed, the patient may seek information on the SCA costs of their drug therapy for a potential reimbursement situation from the SCA Provincial Manager Oncology Drug Programs.

4. CASE-BY-CASE REVIEW PROCESS OF EXTENDED DRUG SUPPLY

STEP	ACTION:
4.1	Prescribing physician/NP applies for a case by case review for an extended drug supply exceeding the current limits identified in APPENDIX A by completing the <i>Aria MO SCA Case-By-Case Extended Drug Supply Request Form note template in Aria MO</i> (APPENDIX C) and submits to the ABCC, CBCR or SCC, CBCR reminder queue.
4.2	<p>Senior Oncology Pharmacist will screen each <i>SCA Case-By-Case Extended Drug Supply Request Form</i> for completeness. In the case of missing information, the pharmacist will contact the requesting Physician/NP as necessary.</p> <p>Please Note:</p> <ul style="list-style-type: none"> ▶ Applications remaining incomplete after 10 days from the date of submission will be closed. <ul style="list-style-type: none"> ▪ The application will be deemed incomplete if any of the mandatory questions on the Request Form are missing.
4.3	<p>Senior Oncology Pharmacist will forward completed submission to DSG Chair and Provincial Manager Oncology Drug Programs and include any decisions of similar past requests.</p> <p><i>*If the requesting physician is the DSG Chair (or no DSG Chair available), the application will be adjudicated by Medical Director, QSDSG of the site from which request is generating.</i></p>
4.4	<p>Upon receipt of a complete application form, DSG Chair and Provincial Manager Oncology Drug Programs will each review the request for:</p> <ul style="list-style-type: none"> - the duration of the patient's absence from the province; - the quantity of extended cancer drug supply required; - assessment by the prescriber that the patient's medical status and tolerance of the cancer drug are sufficient to safely prescribe the extended drug supply; - the proposed monitoring plan – a plan is in place for any investigations that the patient will be required to obtain during the extended medication period for reasons of safe drug use.

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STEP	ACTION:	
	<i>DSG Chair and Provincial Manager Oncology Drug Programs</i> (or designate) provide input/discuss via email and reach consensus within target of 5 business days to approve or deny the request and document the decision.	
	IF	THEN
	If the <i>DSG Chair/ Provincial Manager Oncology Drug Programs</i> <u>do not approve</u> the application	<i>DSG Chair</i> will indicate the decision to deny in the <i>Case-By-Case Extended Drug Supply Decision</i> note template in Aria MO. Prescribing physician/NP will be responsible to explain the decision to the patient.
	If the <i>DSG Chair/ Provincial Manager Oncology Drug Programs</i> <u>approve</u> the application	<i>DSG Chair</i> will indicate the decision to approve the application in a <i>Case-By-Case Extended Drug Supply Decision</i> note template in Aria MO.
	If the <i>DSG Chair</i> and the <i>Provincial Manager Oncology Drug Programs</i> are unable to reach consensus on a decision	<i>DSG Chair</i> forwards the request to same Cancer Centre site Medical Director, QSDSG for final decision.
4.5	If the Medical Director QSDSG <u>does not approve</u> the application	Medical Director QSDSG will <ul style="list-style-type: none"> - indicate the decision to deny in the <i>Case-by-Case Extended Drug Supply Decision</i> note template in Aria MO. - inform the <i>Provincial Manager Oncology Drug Programs</i> (designate) for documentation of the rejection. - Prescribing physician/NP will be responsible to explain the decision to the patient.
	If the Medical Director QSDSG <u>approves</u> the application	Medical Director QSDSG will <ul style="list-style-type: none"> - indicate the decision to approve in the <i>Case-by-Case Extended Drug Supply Decision</i> note template in Aria MO. - inform the <i>Provincial Manager Oncology Drug Programs</i> (designate) for documentation of the approval.
4.6	Once an application has been approved, the Pharmacy staff will make necessary arrangements to support dispensing and treatment.	

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5. MONITORING & REPORTING

STEP	ACTION:
5.1	<i>SCA Pharmacy Provincial Manager Oncology Drug Program</i> shall provide the Director of Oncology Pharmacy and/or the P&T Committee with a Quarterly report of case-by-case approvals and include the file number, diagnosis and cancer medication order approved to allow for identification of any trends or outlier issues.
5.2	If case-by case requests are submitted for a specific cancer medication on more than three (3) occasions in a fiscal year, the P&T Committee may ask the appropriate DSG Chair to review and provide recommendations for future consideration of modifications to the Eligibility of Drugs for Extended Drug Supply list (APPENDIX A).

APPENDIX A

Eligibility of Drugs for Extended Drug Supply

Eligibility of Drugs for Extended Drug Supply			
Maximum Extended Supply	Cancer Drugs Eligible for Extended Supply (*providing conditions in policy are met)		Cancer Drugs <u>NOT</u> Eligible for Extended Supply (beyond 1 cycle or 1 month)
Two (2) Months	afatinib	larotrectinib	cyclophosphamide
	alectinib	lenvatinib	etoposide
	asciminib	lorlatinib	fludarabine
	axitinib	niraparib	lomustine
	azacitidine (Onureg®)	olaparib	melphalan
	brigatinib	osimertinib	mercaptopurine
	cabozantinib	palbociclib	procarbazine
	capecitabine	pegylated interferon	regorafenib
	ceritinib	pomalidomide	sorafenib
	crizotinib	ponatinib	temozolomide
	dabrafenib +/- trametinib	ribociclib	thioguanine
	decitabine/cedazuridine (Inqovi®)	ripretinib	tretinoin
	encorafenib +/- binimetinib	selinexor	
	entrectinib	selpercatinib	
	erlotinib	trametinib +/- dabrafenib	
	everolimus	trifluridine-tipiracil	
	gefitinib	vandetanib	
	gilteritinib	vemurafenib +/- cobimetinib	
lapatinib			
Three (3) Months (**restricted to maximum 84 day supply through Health Canada regulated safety programs)	acalabrutinib	** lenalidomide	Any drug given intravenously that requires administration within a treatment centre will not be provided or dispensed to patients for reasons of extended absence from the province.
	abiraterone	medroxyprogesterone	
	acitretin	megestrol acetate	
	apalutamide	memantine	
	clodronate	methotrexate	
	darbepoetin	mitotane	
	darolutamide	pazopanib	
	denosumab	ruxolitinib	
	enzalutamide	sunitinib	
	fedratinib	venetoclax	
	ibrutinib	** vismodegib	
idelalisib	zanubrutinib		
Four (4) Months	bosutinib		
	chlorambucil		
	nilotinib		
Six (6) Months	anagrelide	imatinib	
	anastrozole	lanreotide (Somatuline Autogel®)	
	bicalutamide	letrozole	
	cyproterone	leuprolide (Eligard® or Lupron®)	
	dasatinib	octreotide LAR	
	degarelix (Firmagon®)	tamoxifen	
	exemestane		
	flutamide		
	fulvestrant		
	goserelin (Zoladex LA®)		
	hydroxyurea		

APPENDIX B

Document of Understanding (Extended Drug Supply)

I am currently receiving medication from the Saskatchewan Cancer Agency prescribed by my cancer doctor. I will be outside of Saskatchewan for an extended period of time and therefore have requested that I be provided with an additional supply of medication.

I understand that:

- The Cancer Agency and my cancer doctor/NP will determine the quantity and type of medication that can be provided to me at any one time.
- If my cancer doctor/NP recommends medical tests (e.g. blood work) to safely use the medication at my destination, it is my responsibility to arrange and pay for the tests and to provide the results to my cancer doctor/NP.
- If the medication is given by injection, it is my responsibility to arrange and pay for injection-related services at my destination.
- If the supply of medication is not sufficient to last until I return to Saskatchewan, it is my responsibility to either:
 - Arrange for medical assessment and purchase medication at my destination; or
 - Return to Saskatchewan for medical assessment and obtain the medication from the Cancer Agency.
- I am responsible to properly store and secure the supply of medication. If the medication is damaged, lost or stolen, it is my responsibility to arrange for and purchase replacement medication with no expectation of reimbursement from the Cancer Agency.

I also understand that:

- I may only be reimbursed by the Cancer Agency for additional supplies of medication purchased at my destination if the medication is part of the Cancer Agency's Drug Formulary. Any reimbursement will be based on the Cancer Agency's price, not the purchase price at my destination.
- I will not be reimbursed by the Cancer Agency for medication that is damaged, lost or stolen.
- Other related medical expenses (e.g. doctor appointments, laboratory tests, medical investigations) will not be reimbursed by the Cancer Agency. If in Canada, these expenses may be covered under The Canada Health Act.

Patient or Legal Representative Signature

My signature confirms that I have read this document and understand the information. I have had the opportunity to ask questions and have had my questions and concerns answered to my satisfaction.

Patient/Legal Representative Signature

Printed Name

Date

Healthcare Practitioner Signature

Printed Name

Date

Copy of document provided to patient

APPENDIX C

Case-By-Case Extended Drug Supply Application Template

Saskatchewan Cancer Agency (SCA) Drug Benefit Program CBCR Extended Drug Supply requests are required for the provision of cancer drug supplies exceeding the quantities provided for in the 'Request for Extended Cancer Drug Supplies Policy'.

****Please ensure to document in all fields; do not leave any fields blank****

<%Current Date%>

****To Be Completed By Requesting Physician****

Proposed Date Extended Supply is to be available (*Must be at least 10 working days from date requested to allow for review and acquisition of required inventory if approved*):

Diagnosis:

Performance Status:

Requested Drug:

Dosage:

Schedule:

Reason for extended supply being requested (*eg. travel*):

Number of Cycles Requested (*adequate to cover the duration of the patient's absence from the province*):

Is the patient's medical status and tolerance of the requested drug sufficient to safely prescribe the extended drug supply?

Are there investigations that the patient will be required to obtain during the period of extended medication supply for reasons of safe drug use?

- Has the patient been informed of any laboratory and/or other medical investigations that would be necessary for safe drug therapy during their extended absence with the understanding that it will be their responsibility to obtain these investigations during their absence (including paying for the investigations, if applicable) and providing the results to their physician?

Plan to evaluate response:

In the case of those drugs administered by intramuscular or subcutaneous injection, the patient is informed and understands their responsibility of obtaining and paying for injection-related services outside of Saskatchewan for when required;

Plan for injection administration:

APPENDIX D

Case-By-Case Extended Drug Supply Decision Note Template

<%Current Date%>

Request: Approved Denied

*****For further details, please see communication from DSG Chair/Director*****

I have reviewed this request with the Pharmacy Provincial Manager of Oncology Drug Programs, or designate, and we are both in agreement with this decision.

Sincerely,

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Policy/Procedure Review & Sign Off

Department	Affected/ impacted department (X)	Name and title of person with whom project has been discussed	Department Sign off	
			Signature	Date
Care/Medical Services				
Nursing	<input checked="" type="checkbox"/>	Bev Kowbel Director Systemic Therapy Outpatient Services	<u>Bev Kowbel</u> <small>Bev Kowbel (Apr 17, 2023 08:46 MDT)</small>	Apr 17, 2023
Pharmacy	<input checked="" type="checkbox"/>	Darryl Boehm Director Oncology Pharmacy	<u>Darryl Boehm</u>	Apr 28, 2023
Clinical Research	<input checked="" type="checkbox"/>	Lynn Dwernychuk Director Clinical Research	<u>Lynn Dwernychuk</u>	Apr 18, 2023
Supportive Care	<input checked="" type="checkbox"/>	Bryan Jorgenson Director Supportive Care	<u>Bryan Jorgenson</u> <small>Bryan Jorgenson (Apr 18, 2023 15:52 MDT)</small>	Apr 18, 2023
Provincial Programs	<input checked="" type="checkbox"/>	Shauna Houshmand Acting Director Provincial Program	<u>Shauna Houshmand</u> <small>Shauna Houshmand (Apr 19, 2023 07:27 MDT)</small>	Apr 19, 2023
Medical Director of Oncology Regina	<input checked="" type="checkbox"/>	Dr. Aslam	<u>Muhammad Aslam</u> <small>Muhammad Aslam (Apr 19, 2023 09:42 MDT)</small>	Apr 19, 2023
Medical Director of Oncology Saskatoon	<input checked="" type="checkbox"/>	Dr. Sami	<u>Dr. Sami</u>	Apr 19, 2023
SCC Director of QSDSG	<input checked="" type="checkbox"/>	Dr. Yadav	<u>Sunil Yadav</u> <small>Sunil Yadav (Apr 28, 2023 11:39 MDT)</small>	Apr 28, 2023
ABCC Director of QSDSG	<input checked="" type="checkbox"/>	Dr Chalchal	<u>Haji Chalchal</u> <small>Haji Chalchal (Apr 28, 2023 12:58 MDT)</small>	Apr 28, 2023
Pediatric Oncology				
Other Divisions				
Other (specify) PFAC	<input checked="" type="checkbox"/>	PFAC Chairperson	<u>Trenna Derdall</u> <small>Trenna Derdall (May 4, 2023 09:00 MDT)</small>	May 4, 2023