BC Cancer Clinical Pharmacy Guide

Case Study Examples

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The following case study examples demonstrate a systematic approach to the clinical review and assessment of cancer drug orders using Module 2: Cancer Drug Order and Assessment.

Checklists of this procedure are found in Appendix A: Clinical Cancer Drug Order Review Checklist - Parenteral and Clinical Cancer Drug Order Review Checklist - Take home.

Summaries of all BC Cancer treatment protocols and preprinted orders can be found on the BC Cancer website (www.bccancer.bc.ca) under **Chemotherapy Protocols**.

Example Case Study 1a: BRAJFEC

Patient D.N. (BC Cancer ID #XX-45678, MRN 0123456XX) is a 48-year-old female in good health, recently diagnosed with breast cancer. The pathology report indicates: invasive lobular carcinoma, high risk, Grade 3, tumor size 2.5 cm, no lymphovascular invasion (0/11 lymph nodes involved), estrogen receptor positive (5/8) and progesterone receptor positive (4/8), HER2 negative. D.N. has had a mastectomy and is scheduled for cancer treatment.

She arrives in preparation for treatment to start on May 27. She had baseline blood tests performed at an outside lab 2 weeks ago, as follows:

Lab results - May 12

WBC	5.3 (x 10^9/L)	Bilirubin	12 (µmol/L)	LDH	409 (U/L)
ANC	4 (x 10^9/L)	Creatinine	55 (µmol/L)	GGT	29 (U/L)
Hgb	120 (g/L)	Alk Phos	93 (U/L)		
Platelets	320 (x 10^9/L)	AST	35 (U/L)		

The Cancer Genetics and Genomics Laboratory has reported that her *DPYD* Predicted Activity Score is 2.0 and her Genotype is variant negative.

Pharmacy received a **written** order on a BRAJFEC preprinted order sheet:

Epirubicin	160 mg IV push
Fluorouracil	800 mg IV push
Cyclophosphamide	800 mg IV in 100 to 250mL NS over 20 to 60 minutes

BSA calculated by the ordering physician is 1.65 m^2 (see height and weight in Step 1).

Step 1: Verify Patient Identity

Two identifiers were used to confirm that the order was written for the correct patient: name (D.N.) and BC Cancer ID number (XX-45678). The BC Cancer ID number verifies that D.N. is registered with BC Cancer. If a BC Cancer ID number is not available, the pharmacist should check with the ordering prescriber or the BC Cancer Registry (1-800-

663-3333 x 674610) to determine if the patient is registered with BC Cancer and BC Cancer benefit drugs can be dispensed.

An independent double check (IDC) and co-signature by a second person of the patient's current height and weight (double signed measurements) are also necessary for Cycle 1 calculation of BSA and cancer treatment dose (see Height and Weight Measurement and Documentation Procedure). The following height and weight were documented in the patient chart on May 26 which were signed by two staff:

Height: 5'5" (165.1 cm)

Weight: 130 lb (59.1 kg)

Step 2: Confirm Protocol Matches Clinical Indication and Eligibility for Treatment

BRAJFEC is a BC Cancer protocol prescribed as adjuvant therapy for breast cancer patients. A current version of this protocol can be found on the BC Cancer website. Before proceeding, always check that you are using the most current version of the protocol by checking the revision date in the footer. It is possible that the protocols themselves may be changed during the course of a patient's treatment. Changes to protocols are announced on the first business day of the month in the Systemic Therapy Update newsletter. Updated and revised protocols are posted online.

The "AJ" in the BR**AJ**FEC protocol name indicates that this is an adjuvant treatment, which refers to any therapy given after the primary treatment, usually surgery, to reduce the risk of cancer recurrence. This protocol has a curative intent.

Determine diagnosis

This information should be available in the physical or electronic chart. If a chart is not available, you may wish to contact the ordering prescriber to confirm that the protocol chosen is consistent with the diagnosis.

In this example, D.N. is diagnosed with breast cancer, with no axillary lymph node involvement.

Does the diagnosis match the eligibility requirements for the protocol?

To be eligible for this treatment, patients must be less than or equal to 60 years of age or a fit patient greater than 60 years of age, with one or more axillary lymph node metastasis(es). Patients may also have high risk, node negative disease to qualify for this protocol.

D.N. is less than 60 years old (48) with high risk disease, and no lymph node involvement. She is in good health and does not have any significant heart disease (an exclusion factor for this protocol). Therefore, the treatment protocol is appropriate for the diagnosis.

The title of the protocol and the "BR" at the beginning of the protocol code indicate that this treatment is for breast cancer so you can proceed with checking the rest of the order. If a lung protocol had been ordered, further investigation would be required (i.e., the prescriber would have to be contacted because the wrong protocol had been ordered, or perhaps the order had been written for the wrong patient).

Benefit status requirements

Is the protocol ordered Class I or Restricted Funding (R)? Protocols with a restricted funding designation require CAP approval through the BC Cancer Compassionate Access Program **prior** to initiation of therapy. Protocols and preprinted orders indicate when CAP approval is required. The BC Cancer Benefit Drug List [Systemic Therapy - Reimbursement & Forms] also indicates the designation for each drug and protocol. Protocol codes are required at the time of drug order entry.

Because D.N. is a resident of British Columbia enrolled in the Medical Services Plan of BC and has been registered with BC Cancer, medications for treatment of her cancer are benefits of the BC Cancer Systemic Therapy Program. The cancer drugs to be administered in this protocol (epirubicin, fluorouracil and cyclophosphamide) are all Class I drugs and the cancer drug protocol does not require any extra documentation regarding benefit status.

Step 3: Review Medical History

Medications, medical history, allergy status and pregnancy status should be confirmed.

D.N. is not currently taking any medications or complementary/alternative medicines. Her past medical history is unremarkable and no external surgeries or treatments that

may conflict are scheduled. She does not have any known allergies. The patient may need to have a negative pregnancy test confirmed or be assessed as not being of "child bearing potential" prior to start of her cancer drug treatment (see Pregnancy Assessment and Education for Systemic Therapy Patients Procedure: V220).

Step 4: Check Timing of Treatment

D.N. has not received any prior treatment for breast cancer. Her first treatment date will be May 27, which will be Day 1 of Cycle 1.

No new concerns have been identified since the treatment orders were written that would warrant reassment of the patient.

Step 5: Determine Patient's Body Surface Area

Calculate the patient's body surface area, using the Mosteller formula:

$$\text{BSA } (m^2) = \sqrt{\frac{height(cm) \times weight(kg)}{3600}}$$

$$= \sqrt{\frac{165.1cm \times 59.1kg}{3600}}$$

$$= 1.65\ m^2$$

Ensure that the patient's body weight and height are the most recent measurements available. For new patients, height and weight measurements must be independently verified and double-signed in accordance with the Height and Weight Measurement and Documentation Procedure.

Step 6: Check Appropriateness of Cancer Drug Dose(s)

Calculation of doses for Cycle 1:

Epirubicin:	100 mg/m^2 × 1.65 m^2 = 165 mg IV
Fluorouracil:	500 mg/m^2 × 1.65 m^2 = 825 mg IV
Cyclophosphamide:	500 mg/m^2 × 1.65 m^2 = 825 mg IV

These calculated doses are within 5% of the doses ordered by the prescriber so the prescriber's orders are acceptable and can be processed as written. If there was a variance of greater than 5%, the prescriber must be contacted and the discrepancy resolved, as per Systemic Therapy Treatment Delivery Process Policy: III-10 [SHOP].

Medications and doses to be administered, must be documented on the patient chart as well as on the pharmacy record.

The suggested maximum cumulative dose for epirubicin is 1000 mg/m^2 according to the BC Cancer epirubicin monograph. The BRAJFEC protocol, however, specifies a maximum of 720 mg/m^2, so this value will be used. For D.N., this would be 720 mg/m^2x 1.65 m^2 = 1188 mg. If the patient received the full six cycles of treatment at full dose, the total epirubicin administered would be 990 mg, which is within the maximum cumulative dose guideline. She has not received any prior cancer drug treatment.

Step 7: Review Laboratory Values

Lab tests are performed routinely throughout treatment, as specified in the protocol. In this example, required testing includes baseline investigations (i.e., prior to the initiation of treatment), assessments before each treatment and additional tests done if clinically indicated.

D.N. has baseline lab results dated May 12. These tests were ordered as outlined in the protocol requirements. The lab results are acceptable for treatment initiation as they were drawn within 4 weeks (28 days) before the start of treatment.

Comparison of lab tests to protocol

D.N.'s lab results are within normal limits so treatment can proceed as ordered.

Her *DPYD* Predicted Activity Score is 2.0 and none of the clinically relevant DPYD variants of concern were detected. She is likely a normal metabolizer and therefore no fluorouracil dose reduction is required.

Step 8: Verify Appropriate Method of Drug Delivery

Prepare and administer as per protocol, following sterile technique and safe handling procedures for hazardous drugs. As indicated in the BRAJFEC protocol, epirubicin and fluorouracil are dispensed in a syringe and administered by IV push. Cyclophosphamide

for IV infusion is dispensed in a 100 mL Normal Saline (0.9% NS) minibag for doses less than or equal to 1000 mg (see the IV Bag Size & Vial Selection table).

Step 9: Monitor for Potential Cancer Drug Toxicity

Epirubicin is a vesicant, pharmacy and nursing staff should review Prevention and Management of Extravasation of Chemotherapy Policy: III-20 [SHOP] prior to administration.

Step 10: Verify Protocol-Related Supportive Care Provided

Antiemetics

The protocol specifies an antiemetic regimen for highly emetogenic chemotherapy (SCNAUSEA). The patient is expected to have received prescriptions for NK_1 and 5-HT_3 antagonists (either Akynzeo® or aprepitant plus ondansetron), dexamethasone, and either olanzapine, prochlorperazine or metoclopramide. These supportive care medications are not supplied or reimbursed by BC Cancer and should be obtained from a community retail pharmacy before treatment begins.

Filgrastim/Pegfilgrastim (G-CSF)

If the patient develops febrile neutropenia while on this protocol, there is an option for the patient to start filgrastim (G-CSF) or long-acting pegylated filgrastim (pegfilgrastim). If the prescriber chooses that option, a completed drug-specific Special Authority Request Form [Systemic Therapy - Reimbursement & Forms] must be submitted to Pharmacare for outpatients. Please note that filgrastim/pegfilgrastim are supportive care medications and their cost is not reimbursed by BC Cancer for **outpatient** use.

BC Cancer does reimburse cost for eligible **inpatients**. The indication for filgrastim is filled in at the time of OSCAR billing by CON hospitals. Filgrastim or pegfilgrastim Special Authority forms are not required for inpatient treatment but may still be completed to facilitate Pharmacare coverage for any future outpatient filgrastim prescriptions dispensed through a community pharmacy for subsequent cycles.

Step 11: Counsel Patient

Patients starting a new protocol require counselling to understand their new cancer medications. For oral medications, pharmacists are required to counsel at the time of dispensing. This patient is starting parenteral medications only. Depending on the cancer centre or CON site, usually a nurse will counsel patients about their parenteral medications. The supportive medications and handouts will be provided by the community pharmacy at the time of dispensing (e.g., Akynzeo®, aprepitant, ondansetron, dexamethasone, etc.).

Resources

Information for Patients

Patient information for specific cancer medications or protocols is available on the BC Cancer website under:

- BRAJFEC Patient Handout
- Cancer Drug Manual Individual Drug Patient Handouts [Drug Index]
    - Cyclophosphamide
    - Epirubicin
    - Fluorouracil

Information for Health Professionals

Detailed information on the medications listed above is available on the BC Cancer website:

- BRAJFEC Protocol
- Cancer Drug Manual [Drug Index]
- ***Chemotherapy Preparation and Stability Chart – Drugs A to K*** [Cancer Drug Manual]
- SCNAUSEA

Other Resources

Protocol patient handouts and individual drug-specific patient handouts often refer to additional symptom and side effect information available elsewhere on the BC Cancer website. Refer to the Pharmacy Symptom and Side Effect Management Resource Guide to access related resources and patient handouts. Other patient specific handouts that may be useful for this patient could include:

- Cancer Drug Manual - Appendix - Information for Patients
    - Natural Health Products and Breast Cancer
    - Sun Sensitivity and Sunscreens
- Coping with Cancer: Nutrition Information
    - Practical Tips to Help Manage Nausea
    - Food Ideas to Help with Taste and Smell Changes
- Coping with Cancer: Managing Symptoms & Side Effects
    - Nausea and Vomiting
    - Managing Fatigue (Tiredness)
- Safe Handling handouts are available and should be provided to this patient as they are receiving a Group 1 Hazardous Drug:
    - Cancer Drug Manual - Safe Handling
        - Guidelines for Handling Cancer Drugs and Body Fluids in the Home
- As this patient is of childbearing potential, the following handout may be useful:
    - Preventing Pregnancy during Cancer Treatment

Subsequent Doses

Cycle 2: First occurrence of low counts, no febrile neutropenia

D.N. returns on June 17 for her second cycle of BRAJFEC. She complains of some mild fatigue but no episodes of fever. Her weight remains the same at 59.1 kg. Subsequent BSA recalculations will be done only if, in the prescriber's opinion, it is warranted by a change in the clinical status of the patient, or if there was a weight change significant enough that it results in a dose variance of greater than 5%, or if there has been a weight change of greater than 10% from Cycle 1 of this regimen.

Cycle 2 BRAJFEC orders were written June 14 (during the oncologist appointment) for administration on June 17:

Epirubicin	160 mg IV push
Fluorouracil	800 mg IV push
Cyclophosphamide	800 mg IV in 100 to 250 mL NS over 20 to 60 minutes

Due to scheduling considerations, patients may be seen several days before their cancer drug administration date, with bloodwork ordered either prior to, or on the day of treatment.

In this case, the prescriber ordered bloodwork for the day of treatment. Generally, the patients are asked to go to the laboratory at least one to two hours prior to their treatment time to allow time for the lab to process and report the results.

Lab results – June 17

WBC	2.0 (x 10^9/L)	Bilirubin	12 (µmol/L)
ANC	1.3 (x 10^9/L)	Creatinine	55 (µmol/L)
Hgb	115 (g/L)		
Platelets	80 (x 10^9/L)		

As this is Cycle 2 of the same protocol that the patient recieved previously, begin the clinical check by considering the timing of the treatment (time interval between Cycle 1 and Cycle 2).

BRAJFEC protocol indicates that this treatment is to be given every 21 days. June 17 is 3 weeks (21 days) from Day 1 of Cycle 1, so the timing of the appointment is appropriate.

Lab work was drawn that morning so timing of lab results is acceptable. However, D.N.'s ANC is low (less than 1.5) and her platelets are low (less than 100). A review of the protocol indicates that the treatment should be delayed by one week. This necessitates a call to the ordering prescriber for further discussion.

Results

The prescriber wrote orders to delay treatment for one week and D.N. is rescheduled to begin Cycle 2 on June 24. Orders for lab work and future appointments are adjusted accordingly. Documentation of this change is recorded on the physical patient chart or Cerner Pharmacy Clinical Check Powerform and the pharmacy treatment record (if applicable). The reason for the treatment delay should also be included in the documentation, as this may influence future treatment decisions, including subsequent dose modifications or scheduling adjustments.

BRAJFEC orders for administration June 24:

Epirubicin	160 mg IV push
Fluorouracil	800 mg IV push
Cyclophosphamide	800 mg IV in 100 to 250 mL NS over 20 to 60 minutes

Timing of appointment is appropriate (delay of one week from previously scheduled date).

- Lab work is within acceptable parameters, i.e., ANC has recovered to greater than or equal to 1.5 and platelets to greater than or equal to 100.
- Doses are within 5% of calculated doses for this protocol.
- According to the *Dose Modifications* Section of the protocol, D.N. can receive 100% of the previous cycle's dose.

Doses can be prepared and administered to patient as ordered; treatment documented in physical or electronic patient chart and pharmacy preparation record.

Cycle 3: Second occurrence of low counts, no febrile neutropenia

D.N. returns on July 15 for Cycle 3 and again, her counts are low. A new order is written to delay her treatment by one week.

Lab results – July 15			
WBC	2.1 (x 10^9/L)	Bilirubin	11 (µmol/L)
ANC	0.95 (x 10^9/L)	Creatinine	57 (µmol/L)
Hgb	115 (g/L)		
Platelets	83 (x 10^9/L)		

D.N. returns on July 22. No episodes of fever; reports moderate fatigue. Timing of appointment is appropriate as ordered. No new labs have been done since July 15. The prescriber is contacted to order bloodwork for July 22.

Lab results and BRAJFEC protocol orders for July 22 are:

Lab results – July 22			
WBC	3.9 (x 10^9/L)	Bilirubin	12 (µmol/L)
ANC	1.6 (x 10^9/L)	Creatinine	55 (µmol/L)
Hgb	115 (g/L)		
Platelets	103 (x 10^9/L)		

Since this delay was after the second occurrence of low counts, the prescriber has ordered 75% of the previous cycle dose per the protocol's *Dose Modification* section:

Epirubicin	120 mg IV push
Fluorouracil	600 mg IV push

Cyclophosphamide	600 mg IV in 100 to 250 mL NS over 20 to 60 minutes

All written doses are acceptable, so medication may be prepared and administered as ordered and documentation completed as in previous cycles.

Cycle 4

D.N. returns for Cycle 4 on August 12 and lab tests are ordered that morning.

BRAJFEC protocol orders for August 12 are:

Epirubicin	120 mg IV push
Fluorouracil	600 mg IV push
Cyclophosphamide	600 mg IV in 100 to 250 mL NS over 20 to 60 minutes

The treatment interval and lab results are appropriate and bloodwork is within acceptable limits. The patient had a 75% dose reduction in the previous cycle and will continue further cycles at this dose.

Doses are prepared and administered as ordered. Documentation is completed.

Cycles 5 and 6

D.N. does not experience any other treatment delays for the remaining two cycles of this protocol and her chemotherapy treatment is completed.

Note: if the prescriber were to order a 7th cycle, prior approval from the **Compassionate Access Program** [Systemic Therapy] would be required as the protocol indicates a total of 6 cycles only under the *Treatment* section. Approval must be granted before the patient is eligible to receive further treatment.

Example Case Study 1b: BRAVDOC

Four years later, D.N., now 52 years old, returns complaining of bone pain and shortness of breath. A diagnosis of metastatic disease with pulmonary and osseous involvement is confirmed by CT and bone scan. She is scheduled to receive cancer drug treatment with the BRAVDOC protocol on May 22.

Lab work – May 8 (2 weeks prior to first cycle of treatment)

WBC	7 (x 10^9/L)	Bilirubin	10 (µmol/L)
ANC	3.9 (x 10^9/L)	Alk Phos	69 (U/L)
Hgb	128 (g/L)	ALT	24 (U/L)
Platelets	216 (x 10^9/L)	AST	30 (U/L)

Written orders received on a BC Cancer preprinted order.

Treatment plan: Docetaxel 155 mg IV every 21 days, as indicated in the BRAVDOC protocol.

Step 1: Verify Patient Identity

D.N. is still a B.C. resident and retains her previously assigned BC Cancer ID number (XX-45678). Two identifiers were used to confirm that the order was written for the correct patient: name (D.N.) and BC Cancer ID number (XX-45678). Patient-specific information: height 165 cm, weight 115 lbs (52.3 kg), as of May 8. The height and weight were confirmed to be current and double-signed again since her last independently double checked (IDC) recorded measurements were done four years ago (see Height and Weight Measurement and Documentation Procedure.) Her ECOG performance status is 1.

Step 2: Confirm Protocol Matches Clinical Indication and Eligibility for Treatment

BRAVDOC is a BC Cancer protocol used for treatment of advanced breast cancer. The current version of this protocol can be found on the BC Cancer website. Once again, ensure that you are using the most current version.

The "AV" in the BR**AV**DOC protocol name indicates that this is treatment for advanced, metastatic cancer.

Determine diagnosis

D.N. was treated with 6 cycles of BRAJFEC four years ago, for primary treatment of breast cancer. Diagnosis for metastatic disease has been confirmed by a bone scan (osseous involvement) and CT scan (pulmonary involvement).

Does the diagnosis match the eligibility requirements for the protocol?

In the eligibility section of the BRAVDOC protocol, there is a list of approved indications for the use of this protocol. D.N. is eligible for this treatment based on a diagnosis of metastatic breast cancer, ECOG status of 1, and a life expectancy greater than 3 months.

Benefit status requirements

The first 8 cycles of the BRAVDOC protocol has a Class I indication; however further cycles would require approval from the **Compassionate Access Program** [Systemic Therapy] prior to the patient receiving cycle 9.

Step 3: Review Medical History

Medications, medical history, allergy status and pregnancy status should be reviewed and confirmed.

D.N. does not take other medications or complementary/alternative medicines. Her past medical history is otherwise unremarkable with no non-oncology conditions (such as active infection) and external surgeries or treatments that may conflict. She confirms she still does not have any known allergies. She will need to have a negative pregnancy test confirmed or be assessed as not being of "child bearing potential" prior to the start of her cancer drug treatment (see Pregnancy Assessment and Education for Systemic Therapy Patients Procedure: V220).

Step 4: Check Timing of Treatment

Previous treatment was four years ago. This is her first cycle of treatment for relapse. Her first treatment date will be May 22.

No new concerns that may require the patient to be reassessed occurred since the orders were written.

Step 5: Determine Patient's Body Surface Area

Calculate body surface area using the Mosteller formula:

$$\text{BSA } (m^2) = \sqrt{\frac{height(cm) \times weight(kg)}{3600}}$$

$$= \sqrt{\frac{165cm \times 52.3kg}{3600}}$$

$$= 1.55\ m^2$$

Step 6: Check Appropriateness of Cancer Drug Dose(s)

Dose calculation for Cycle 1:

Using 100 mg/m^2, as indicated in the BRAVDOC protocol, the docetaxel dose is calculated to be 155 mg, as prescribed (no dose variance). Medication and dose to be administered must be documented on the patient chart as well as on the pharmacy treatment record. Docetaxel does not require monitoring for cumulative dosing.

Proceed with checking the lab work as per Systemic Therapy Treatment Delivery Process Policy: III-10 [SHOP].

Step 7: Review Laboratory Values

Lab work for current treatment is from 2 weeks ago. The lab work is acceptable because it was drawn within the required 4 weeks (28 days) of starting Cycle 1 of treatment. All baseline tests have been ordered.

Comparison of lab tests to protocol

All lab values fall within normal range so treatment can proceed as ordered.

Step 8: Verify Appropriate Method of Drug Delivery

The protocol indicates docetaxel 100 mg/m^2 should be administered IV in 250-500 mL NS or D5W over 1 hour using non-DEHP equipment. In accordance with the Cancer Drug Manual's Chemotherapy Preparation and Stability Chart (diluent) and IV Bag Size Selection Table (bag size), docetaxel 155 mg would be prepared in a 250 mL non-DEHP NS bag.

Step 9: Monitor for Potential Cancer Drug Toxicity

The duration of infusion for docetaxel is designated as 1 hour; however, there are precautions, due to risk of infusion-related reactions. For docetaxel, a prescriber must remain on site for 30 minutes following the start of the infusion for every treatment. Refer to Infusion Related Drug Reaction Management – Physician or Nurse Practitioner Coverage During Delivery of Selected Systemic Therapy Drugs Policy: III-60 and associated Appendices [SHOP] for more information. Although this is not directly a pharmacy consideration, pharmacists should be aware of these precautions. Treatment appointments must be scheduled during a time when a prescriber is present in the facility.

Docetaxel is an irritant and can cause pain and local tissue necrosis if extravasated, as indicated under *Precautions* section in the protocol and Prevention and Management of Extravasation of Chemotherapy Policy: III-20 [SHOP].

Docetaxel-induced onycholysis (nail changes) and cutaneous toxicity of the hands may be prevented by w earing frozen gloves starting 15 minutes before docetaxel infusion and continuing for 15 minutes following the docetaxel infusion. Frozen gloves should be replaced after 45 minutes of wearing to ensure that the hands remain cold during the entire docetaxel infusion.

Step 10: Verify Protocol-Related Supportive Care Provided

Dexamethasone is given to reduce fluid retention and to reduce the severity of the infusion-related reactions as well as cutaneous toxicity associated with docetaxel administration.

As specified in the protocol, the dexamethasone dose is 8 mg PO BID for 3 days, starting one day prior to each docetaxel administration. Patient must receive a minimum of 3 doses of dexamethasone prior to docetaxel administration. Pharmacy

staff may wish to have confirmation that the patient has taken their premedications appropriately, prior to preparing the cancer drug treatment.

Supportive care medications are not reimbursed by BC Cancer, and should be obtained from a community retail pharmacy before treatment begins. Additional antiemetics are not usually required with this protocol.

Step 11: Counsel Patient

Patients starting a new protocol require counselling to understand their new cancer medications. For oral medications, pharmacists are required to counsel at the time of dispensing. This patient is starting parenteral medications only. Depending on the cancer centre or CON site, usually a nurse will counsel patients about their parenteral medications.

Resources

Drug Information

Information for the BRAVDOC protocol and docetaxel can be found for patients and health professionals on the BC Cancer website under:

- BRAVDOC Patient Handout and Chemotherapy Protocol
- Cancer Drug Manual Individual Drug Monographs and Patient Handouts [Drug Index]
    - Docetaxel

Other Resources

Protocol patient handouts and individual drug-specific patient handouts often refer to additional symptom and side effect information available elsewhere on the BC Cancer website. Refer to the Pharmacy Symptom and Side Effect Management Resource Guide to access related resources and patient handouts.

Subsequent Doses

D.N. continues treatment and is now at her third cycle. She presents 21 days following her 2nd cycle, on July 3, with lab work taken the same day.

Lab results – July 3			
WBC	2.5 (x 10^9/L)	Hgb	116 (g/L)
ANC	0.93 (x 10^9/L)	Platelets	103 (x 10^9/L)

Treatment is delayed for 1 week due to low ANC, with lab work reordered, including liver enzymes.

D.N. returns 1 week later, July 10, with the following lab work:

Lab results – July 10			
WBC	3.3 (x 10^9/L)	Alk Phos	257 (U/L)
ANC	1.4 (x 10^9/L)	ALT	123 (U/L)
Hgb	118 (g/L)	AST	88 (U/L)
Platelets	140 (x 10^9/L)	Bilirubin	20 (µmol/L)

Her weight has decreased to 50 kg; however, the prescriber decided that a recalculation of BSA was not required, and the BSA remained (1.55 m^2) the same as previously calculated.

Due to continued low ANC, and elevated hepatic enzymes, a dose reduction to 75% of the dose is ordered. The new dose is calculated to be 116 mg. As the weight change is less than 10%, and a recalculated dose (using the new lower weight and BSA) would still fall within 5% of the ordered dose of 116 mg, pharmacy proceeds with the dose as ordered.

D.N. continues treatment without delay or any further dose reductions. She receives a total of 8 cycles, as indicated in the treatment protocol.

Note: if the prescriber were to order a 9th cycle, this would require approval from the **Compassionate Access Program** [Systemic Therapy]. Approval must be granted *prior* to the patient receiving cycle 9.

Example Case Study 2: Oral Cancer Drug Treatment with LUAVERL

Patient B.B. (BC Cancer ID #XX-12345) is a 69-year-old female non-smoker, who has recently been diagnosed with metastatic lung adenocarcinoma. She arrives on June 21 in pharmacy with a prescription for erlotinib.

She had baseline blood tests performed at a community lab 2 weeks ago, as follows:

Lab results - June 7

WBC	4.4 (x 10^9/L)	Bilirubin	4 (µmol/L)	GGT	16 (U/L)
ANC	2.8 (x 10^9/L)	Creatinine	63 (µmol/L)	LDH	231 (U/L)
Hgb	131 (g/L)	Alk Phos	135 (U/L)	Albumin	39 (U/L)
Platelets	312 (x 10^9/L)	AST	25 (U/L)	CRP	1 (mg/L)

Pharmacy received a written order on a BC Cancer preprinted order for the LUAVERL protocol requesting the following:

Erlotinib 150 mg PO daily for 28 days

Step 1: Verify Patient Identity

Has the patient been registered with BC Cancer? B.B. has a BC Cancer ID number (XX-12345) and is therefore a registered patient with BC Cancer.

Two identifiers can be used to confirm that the order was written for the correct patient: name (B.B.) and BC Cancer ID number (XX-12345) or Personal Health Number (PHN).

If the patient is dropping off the prescription in person, date of birth, allergy status and height and weight (if applicable) can also be confirmed with the patient at this time.

Step 2: Confirm Protocol Matches Clinical Indication and Eligibility for Treatment

LUAVERL is a BC Cancer protocol currently in use for treatment of advanced non-small cell lung cancer (NSCLC). The most current version of this protocol is found on the BC Cancer website. Before proceeding, ensure that you are referring to the most current version of the protocol and the preprinted order.

"AV" in the protocol name indicates that this is treatment for advanced, metastatic cancer. This information should be available in the chart or electronic health record. If a chart is not available, you may wish to contact the ordering prescriber to confirm that those written orders are consistent with the indication on the protocol.

In this example, B.B. is diagnosed with metastatic lung adenocarcinoma which is a non-small cell lung cancer (NSCLC).

The protocol eligibility section indicates that patients must have progressive disease on or after first or second line therapy for advanced NSCLC. B.B's medication history indicates that she was previously on carboplatin and gemcitabine (LUAVPG). Her disease progressed after 4 cycles.

Is erlotinib Class I, or does it require CAP approval? The LUAVERL protocol indicates that erlotinib for second or third line treatment of metastatic NSCLC is Class I. This information can also be confirmed using the BC Cancer Benefit Drug List.

Erlotinib has been prescribed as a second line therapy for B.B., and is considered a Class I benefit drug. No additional documentation regarding benefit status is required with this protocol. If erlotinib were prescribed as first line therapy, approval from the BC Cancer Compassionate Access Program (CAP) would be required prior to treatment initiation.

Because B.B is a registered patient with BC Cancer and is a resident of British Columbia, erlotinib, for treatment of her cancer is eligible for reimbursement through the BC Cancer Systemic Therapy Program.

Step 3: Review Medical History

Medications, medical history, allergy status should be reviewed and confirmed. As B.B's age is above 56, pregnancy assessment documentation is not indicated.

B.B.'s PharmaNet profile indicates she is currently taking levothyroxine, allopurinol, ranitidine, ramipril and oxazepam. The *Interactions* section of the Cancer Drug Manual

erlotinib monograph notes that H2-blockers may reduce erlotinib solubility by increasing gastric pH (potentially reducing its therapeutic effectiveness). Separating the administration times of the two drugs is recommended. The Lexicomp and Micromedex drug interaction databases also identify this interaction. The patient should be counselled on appropriately spacing the administration of ranitidine and erlotinib. Alternatively, the possibility of discontinuing ranitidine could be discussed with her family doctor. In this case, waiting for direction from the prescribers of ranitidine and erlotinib is not required. However the pharmacist should document the intervention and communicate the outcome of the drug interaction assessment, including any counselling provided and recommendations made to the patient, to the relevant prescribers via email or fax communication. See Step 11 for the counselling details.

Her past medical history is otherwise unremarkable with no non-oncology conditions or external surgeries or treatments that may conflict. She does not have any known allergies. She is not required to do a pregnancy test prior to start of her cancer drug therapy as she is considered “not of child bearing potential”.

Step 4: Check Timing of Treatment

B.B. received her last treatment with LUAVPG on May 3. Her first dose of erlotinib will be on June 21, which will be Day 1 of Cycle 1 for this new treatment. The planned schedule is appropriate.

Step 5: Determine Patient’s Body Surface Area (if applicable)

A BSA calculation is not necessary as erlotinib dosing is fixed and not based on BSA.

Step 6: Check Appropriateness of Cancer Drug Dose(s)

The dose written for erlotinib is 150 mg daily, which is the correct starting dose according to the protocol.

Step 7: Review Laboratory Values

Lab tests are performed at various times throughout treatment, depending on the protocol. In this example, there are baseline tests (i.e., prior to the initiation of treatment), tests two weeks after initiation of therapy and tests before each subsequent

visit. B.B. has lab results dated June 7. These baseline tests have been ordered, as outlined in the protocol. The lab work is acceptable because it was drawn within 4 weeks (28 days) of starting treatment.

All of B.B's lab results are within normal limits so treatment can proceed as ordered.

Step 8: Verify Appropriate Method of Drug Delivery

B.B. has no problems swallowing tablets, so erlotinib oral tablets are a suitable dosage form.

Step 9: Monitor for Cancer Drug Toxicity

The pharmacist will provide and use the BC Cancer patient handout for erlotinib to counsel B.B. in Step 11. B.B. will be booked to return for assessment by the prescriber prior to Cycle 2. She is provided with contact information for the nursing line and pharmacy, and instructed to contact the cancer clinic with any concerns that may occur prior to the return appointment if needed.

The protocol *Dose Modifications* section suggests dose interruption or modification for rash, diarrhea and elevated liver enzymes. The protocol *Precautions* section gives information on severe skin toxicity, diarrhea, gastrointestinal perforation risk, and ocular disorders. The erlotinib patient handout and drug monograph list further common side effect information that can be used for monitoring toxicities and for counselling the patient on what to watch for.

Step 10: Verify Protocol-Related Supportive Care Provided

Refer to the protocol for information about required premedication or supportive care. No antiemetic prescription is required. The erlotinib monograph indicates that the emetogenic potential is rare. However, the ordering prescriber may prescribe an antiemetic if they feel the patient is at risk.

B.B. is quite anxious about nausea and vomiting because she had a lot of trouble with it during her previous cancer drug regimen and she also reports a history of motion sickness. As no antiemetic had been prescribed, the pharmacist contacted the prescriber and a prescription for prochlorperazine 10 mg every 4 to 6 hours as needed was provided and sent to the patient's local community pharmacy.

Step 11: Counsel Patient

Patients starting a new protocol require counselling to understand their new cancer medications. For oral medications, pharmacists are required to counsel at the time of dispensing.

The pharmacist provided and reviewed the BC Cancer erlotinib patient handout with B.B. to counsel her regarding administration instructions, precautions and common side effects, including nausea/vomiting, diarrhea, skin rash, sore mouth and fatigue.

A drug interaction between ranitidine and erlotinib was flagged for discussion with B.B, and she was counselled to separate the administration of her twice daily ranitidine and once daily erlotinib by taking erlotinib at least 2 hours before or 10 hours after ranitidine. B.B. was also counselled to avoid grapefruit and grapefruit juice because it can increase the serum erlotinib concentration by inhibiting CYP3A4 enzymes in the intestinal wall. The erlotinib patient handout and information regarding the ranitidine - erlotinib drug interaction were provided to her for reference and to facilitate discussion with her family doctor.

The counselling is documented per site procedures.

Resources

Information for Patients

Information for the patient on the medication can be found on the BC Cancer website under:

- Erlotinib Patient Handout
- LUAVERL Patient Handout
- Nausea and Vomiting [Pharmacy Symptom & Side Effect Management Resource Guide]

The pharmacist is encouraged to review this information with the patient.

Information for Health Professionals

Detailed information on the medication for health professionals is available on the BC Cancer website under:

- LUAVERL Chemotherapy Protocol
- Erlotinib Drug Monograph

Other Resources

Protocol patient handouts and individual drug-specific patient handouts often refer to additional symptom and side effect information available elsewhere on the BC Cancer website. Refer to the Pharmacy Symptom and Side Effect Management Resource Guide to access related resources and patient handouts.

Other patient specific handouts that may be useful for this patient could include:

- Cancer Drug Manual Appendix [Information for Patients]
    - Natural Health Products and Cancer Therapy
    - Sun Sensitivity and Sunscreens
- Coping with Cancer: Nutrition Information
    - Food Choices to Help Manage Diarrhea Caused by Cancer Treatment
    - Food Ideas for a Sore Mouth
    - Practical Tips to Help Manage Nausea
    - Food Ideas to Help with Decreased Appetite
- Coping with Cancer: Managing Symptoms & Side Effects
    - Nausea and Vomiting
    - Managing Fatigue (Tiredness)

Subsequent Doses

Cycle 2

B.B. returns on July 19 with a prescription for erlotinib 100 mg daily for 28 days. Her bloodwork was drawn that morning. You notice that she has a maculopapular rash on her face. She did not have any other problems related to her first cycle of treatment.

Her weight remains at 59 kg.

Lab results – Jul 18			
Bilirubin	3 (µmol/L)	Alk Phos	124 (U/L)
AST	28 (U/L)	LDH	223 (U/L)

As this is a continuation of the previous treatment, reviewing the patient's cancer drug order can begin with timing of the treatment. This appointment has been scheduled 28 days from Day 1 of Cycle 1 so the timing is appropriate.

When checking the dose for Cycle 2, the pharmacist notes that the dose has been reduced to 100 mg daily. The prescriber's dictation reveals that the dose was reduced because the patient developed a maculopapular rash during Cycle 1. Although B.B. started minocycline mid-cycle, the rash progressed. Together, B.B. and her health care team made the decision to reduce the erlotinib dose. The protocol indicates that rash may require treatment interruption and/or dose reduction. The dose reduction to 100 mg daily is consistent with the protocol recommendations for rash management.

Lab work is acceptable and within normal limits as specified in the protocol.

Cycle 3

B.B. returned for consideration of Cycle 3 on Aug 16. Her rash has improved considerably and her LFTs are normal.

Lab results – Aug 15

Bilirubin	5 (µmol/L)
Alk Phos	119 (U/L)
AST	27 (U/L)
LDH	241 (U/L)

B.B. is tolerating erlotinib well and her treatment is continued at the reduced dose of 100 mg daily for 28 days.

Cycle 4

B.B. returned to clinic on Sep 13 for consideration of Cycle 4. A CT scan from the week prior showed evidence of tumor progression. Erlotinib was discontinued and further treatment with docetaxel was considered.

Example Case Study 3: GIFOLFOX

The following example demonstrates that deviation from the protocol can occur.

A.C. (MRN 111222XXX) is a 43-year-old female, diagnosed with carcinoma of the sigmoid colon, previously treated with surgery and post-op chemotherapy (12 cycles of GIAJFL) completed in August of the previous year. She returns to clinic, now diagnosed with metastatic disease (hepatic involvement) and is scheduled for treatment with GIFOLFOX on March 12. Baseline blood tests were performed at a community lab 3 weeks ago. A.C. is not taking any other medications.

Lab results - February 18

WBC	13.7 (x 10^9/L)	Creatinine	60 (µmol/L)	Electrolytes	WNL*
ANC	10.23 (x 10^9/L)	Bilirubin	20 (µmol/L)	Ca, Mg	WNL
Hgb	124 (g/L)	AST	40 (U/L)		
Platelets	495 (x 10^9/L)	Alk Phos	203 (U/L)		

(* Within Normal Limits)

Step 1: Verify Patient Identity

Pharmacy has received a written order for the following:

Oxaliplatin 130 mg IV in 500 mL D5W over 2 hours
Leucovorin 600 mg IV in 250 mL D5W over 2 hours
Fluorouracil 600 mg IV push, after Leucovorin, THEN
Fluorouracil 3600 mg by continuous IV infusion over 46 hours

A.C's name, DOB and MRN number were confirmed on the order, as A.C. is returning for treatment.

Patient-specific information: double signed height 150 cm, weight 55 kg, as available in the chart from March 11 (see Height and Weight Measurement and Documentation Procedure).

Step 2: Confirm Protocol Matches Clinical Indication and Eligibility for Treatment

GIFOLFOX is a BC Cancer protocol currently in use for second line palliative combination treatment of metastatic colorectal cancer. Before proceeding, ensure that the protocol version you are using is the most current.

This protocol includes numerous eligibility criteria and cautions. The term colorectal encompasses both colon and rectal cancers. None of the cautions listed in the protocol apply to this patient and all other criteria are met. A.C. has metastatic adenocarcinoma of the sigmoid colon and is receiving first-line treatment in the advanced setting, having previously received protocol GIAJFL in the adjuvant setting. Therefore, A.C. is eligible for the GIFOLFOX protocol, based on her diagnosis and treatment history.

This protocol involves treatment with a 46h continuous IV infusion of fluorouracil every two weeks, physicians generally order a central venous access device insertion prior to treatment. A.C. has already had her central line (PORT-a-Cath) inserted and is ready for Cycle 1.

Step 3: Review Medical History

Medications, medical history, allergy status and pregnancy status should be reviewed and confirmed.

A.C. is not taking any other medications. Her past medical history is otherwise unremarkable with no non-oncology conditions (such as active infection) or external surgeries or treatments that may conflict.

A.C. has a history of severe latex allergy. All her medications must be prepared following the Provincial Pharmacy Directive VI-70: Guidelines for Preparation of Parenteral Hazardous Drugs for Latex Allergy Patients [SHOP]. Her latex allergy must be documented on her medical record and pharmacy file, as well as on all pharmacy labels used for preparation and dispensation of her IV drugs.

She will need to have a negative pregnancy test confirmed or be assessed as not being of “child bearing potential” prior to start of her cancer drug treatment (see Pregnancy Assessment and Education for Systemic Therapy Patients Procedure: V220).

Step 4: Check Timing of Treatment

A.C. previously received treatment, which was completed 6 months ago. This is her first cycle of treatment in the advanced setting. Her treatment start date is March 12.

Step 5: Determine Patient's Body Surface Area

Calculate the patient's body surface area:

$$\text{BSA } (m^2) = \sqrt{\frac{height(cm) \times weight(kg)}{3600}}$$

$$= \sqrt{\frac{150cm \times 55kg}{3600}}$$

$$= 1.51\ m^2$$

Step 6: Check Appropriateness of Cancer Drug Dose(s)

Calculation of doses for Cycle 1:

Oxaliplatin: 85 mg/m^2 × 1.51 m^2 = 128 mg
Leucovorin: 400 mg/m^2 × 1.51 m^2 = 604 mg
Fluorouracil bolus: 400 mg/m^2 × 1.51 m^2 = 604 mg
Fluorouracil infusion: 2400 mg/m^2 x 1.51 m^2 = 3624 mg

These calculated doses are within 5% of the doses ordered by the prescriber and are therefore acceptable, as per Systemic Therapy Treatment Delivery Process Policy: III-10 [SHOP]. If the dose variance exceeds 5%, the prescriber must be contacted to resolve the discrepancy. The order will be processed as written by the prescriber. Note: Due to dose banding, the infusional fluorouracil will be dispensed in a Baxter LV5 Infusor® containing 3600 mg of fluorouracil, as per the dose banding table in the protocol. Refer to the Pharmacy FAQ – Dose Banding for further information.

Doses administered should be documented on the patient chart, as well as on the pharmacy treatment record.

The patient is not receiving a drug with a recommended maximum cumulative dose.

Step 7: Review of Laboratory Values

Lab results for Cycle 1 of this treatment were drawn 3 weeks ago prior to treatment initiation. In accordance with BC Cancer Systemic Therapy Treatment Delivery Process Policy: III-10 [SHOP], these results are acceptable as they were collected within 4 weeks (28 days) of the start of treatment.

A.C.'s lab results are within the guidelines of this protocol and treatment can proceed as ordered. WBC and ANC counts were slightly high but her vitals including temperature were checked to ensure she did not have an infection prior to starting chemotherapy.

As A.C. has previously received fluorouracil in the adjuvant setting and tolerated therapy, DPYD testing is not required as part of the baseline testing for this patient.

Step 8: Verify Appropriate Method of Drug Delivery

Prepare and administer as per protocol, following sterile technique and safe handling procedures for hazardous drugs. As per protocol, oxaliplatin and leucovorin are administered in D5W and may be given concurrently by using a Y-site connector placed immediately before the injection site. Oxaliplatin and leucovorin cannot be combined in the same bag, and oxaliplatin is not compatible with NS, as per the *Chemotherapy Preparation and Stability Chart* [Cancer Drug Manual]. The first dose of fluorouracil is administered as intravenous (IV) bolus, followed by a second dose given as a 46-hour continuous infusion. The GIFOLFOX preprinted orders indicate that BC Cancer uses Baxter LV5 infusors™ to infuse fluorouracil for this protocol.

The drug formulations and devices used for this patient will have to be assessed for latex content prior to mixing per usual site procedures. Refer to Provincial Pharmacy Directive VI-70: Guidelines for Preparation of Parenteral Hazardous Drugs for Latex Allergy Patients [SHOP].

Step 9: Monitor for Potential Cancer Drug Toxicity

Leucovorin

As part of the protocol, leucovorin plays a supportive role in treatment. Read the *Protectants* section of the pharmacy Supportive Care module [Clinical Pharmacy Guide – Modules – Module 5] for more information.

Step 10: Verify Protocol-Related Supportive Care Provided

Anti-emetics

GIFOLFOX is classified as "Moderately Emetogenic Chemotherapy (MEC)" as per the updated BC Cancer Supportive Care Protocol SCNAUSEA. Ondansetron and dexamethasone are indicated as premedication, and the patient should have been given a prescription for these drugs to be filled at a community retail pharmacy. Prochlorperazine, metoclopramide, and olanzapine may also be prescribed for this patient. Read the *Antiemetics* section of the pharmacy Supportive Care module [Clinical Pharmacy Guide - Modules – Module 5] for more information. Supportive care medications are not reimbursed by BC Cancer, and should be obtained from a community retail pharmacy before treatment begins.

Loperamide

Both oxaliplatin and fluorouracil have the potential to cause diarrhea. When used in combination, this potential increases. Loperamide may be needed as a supportive care medication option for this patient. Patients should be counselled to have loperamide readily available at home prior to starting treatment to allow prompt management of diarrhea. Supportive care medications are not reimbursed by BC Cancer, and must be obtained from a community retail pharmacy before treatment begins. See the BC Cancer pharmacy Drug Funding web page for more information.

Step 11: Counsel Patient

Patients starting a new protocol require counselling to understand their new cancer medications. For oral medications, pharmacists are required to counsel at the time of dispensing. This patient is starting parenteral medications only. Depending on the cancer centre or CON site, usually a nurse will counsel patients about their parenteral medications.

Resources

Information for Patients

Information for the patient on the medications can be found on the BC Cancer website under:

- GIFOLFOX Patient Handout
- Fluorouracil INFUSOR™ Patient Handout (Your Infusor – A Guide for Patients)
- Cancer Drug Manual Individual Patient Handouts [Drug Index]:
    - Oxaliplatin
    - Leucovorin
    - Fluorouracil
    - Ondansetron
    - Metoclopramide
    - Prochlorperazine
    - Dexamethasone
- Nausea and Vomiting [Pharmacy Symptom & Side Effect Management Resource Guide]

Information for Health Professionals

Detailed information on the protocol and medications is available on the BC Cancer website under:

- GIFOLFOX Protocol
- Cancer Drug Manual
    - Chemotherapy Preparation & Stability Charts
    - Drug Index - Individual Drug Monographs
        - Oxaliplatin
        - Leucovorin
        - Fluorouracil (5-FU)
        - Ondansetron
        - Metoclopramide
        - Prochlorperazine
        - Dexamethasone
- Pharmacy FAQs
    - Dose Banding
    - Elastomeric Infusors for fluorouracil (5-FU)

Other Resources

Protocol patient handouts and individual drug-specific patient handouts often refer to additional symptom and side effect information available elsewhere on the BC Cancer

website. Refer to the Pharmacy Symptom and Side Effect Management Resource Guide to access related resources and patient handouts.

Other patient specific handouts that may be useful for this patient could include:

- Cancer Drug Manual Appendix [Information for Patients]
    - Natural Health Products and Cancer Therapy
    - Sun Sensitivity and Sunscreens
- Coping with Cancer: Nutrition Information
    - Food Choices to Help Manage Diarrhea Caused by Cancer Treatment
    - Food Ideas for a Sore Mouth
    - Food Ideas to Help with Decreased Appetite
    - Practical Tips to Help Manage Nausea
- Coping with Cancer: Managing Symptoms & Side Effects
    - Nausea and Vomiting
    - Managing Fatigue (Tiredness)
- Safe Handling handouts are available and should be provided to this patient as they are receiving a Group 1 Hazardous Drug:
    - Cancer Drug Manual [Safe Handling]
        - Guidelines for Handling Cancer Drugs and Body Fluids in the Home
- As this patient is of childbearing potential, the following handout may also be useful:
    - Preventing Pregnancy during Cancer Treatment

Subsequent Doses

Cycle 3: April 9

A.C. returns for her third cycle of treatment. Her previous treatment was on March 26. She has been troubled with diarrhea and mucositis. Since the patient has been heavily pretreated with 5-FU, the prescriber decides to reduce the 5-FU dose by one dose level. She is also experiencing Grade 2 level peripheral neuropathy and pharyngeal dysesthesia. According to the protocol *Dose Modification* guidelines, the dose of oxaliplatin should be decreased by one dose level. However, based on patient-specific factors and clinical experience, the prescriber decides to continue at the present oxaliplatin dose. As the rationale for this deviation from protocol is not clearly

documented in the prescriber's clinic note, the pharmacist contacts the prescriber to confirm the treatment plan. The decision is verified and documented in the pharmacy treatment record and patient chart.

Lab results – April 8

WBC	7.7 (x 10^9/L)	Bilirubin	8 (µmol/L)	Electrolytes	WNL
ANC	3.44 (x 10^9/L)	AST	41 (U/L)	Ca, Mg	WNL
Hgb	126 (g/L)	Alk Phos	69 (U/L)		
Platelets	185 (x 10^9/L)	Creatinine	70 (µmol/L)		

Her current weight is 51.8 kg. The doses still remain within 5% of the doses ordered and her weight change is not greater than 10% from Cycle 1. As per Systemic Therapy Treatment Delivery Process Policy: III-10 [SHOP], the prescriber has chosen to keep using the same BSA (1.51 m^2) as previously calculated. Pharmacy receives the following orders:

Oxaliplatin 130 mg IV in 500 mL D5W over 2 hours
Leucovorin 600 mg IV in 250 mL D5W over 2 hours
Fluorouracil 480 mg IV push
Fluorouracil 3000 mg continuous IV infusion over 46 hours

Calculated doses are as follows:

Oxaliplatin: 1.51 m^2 x 85 mg/m^2 = 128 mg
Leucovorin: 1.51 m^2 x 400 mg/m^2 = 604 mg
Fluorouracil bolus: 1.51 m^2 x 320 mg/m^2 = 483 mg
Fluorouracil infusion: 1.51 m^2 x 2000 mg/m^2 = 3020 mg

The calculated doses are within 5% of the ordered doses, and therefore are acceptable. Doses can be prepared as ordered by the prescriber and administered to patient. Due to dose banding, the infusional fluorouracil will be dispensed in a Baxter LV5 Infusor® containing 3200 mg of fluorouracil.

Cycle 5: May 21

A.C. returns for consideration of her 5th cycle of treatment. Her previous cycle was completed on April 23. One week later she was hospitalized for severe abdominal pain, diarrhea, nausea and vomiting, with mild dehydration. She remained in hospital for

more than one week and as a result her treatment scheduled for May 7 was cancelled. When A.C is reassessed on May 21, her neurotoxicity is at Grade 3 and, according to the protocol, oxaliplatin should be discontinued. However, based on clinical judgement and patient-specific factors, the prescriber decides to continue oxaliplatin treatment, at one dose level lower than previously administered. The prescriber also believes that her hospitalization was related to fluorouracil toxicity, and therefore, decreases the fluorouracil dose by an additional dose level. Because these protocol deviations are not clearly documented in the prescriber's clinic note the pharmacist contacts the presctiber to confirm the treatment plan and rationale then documents the clarified information in the pharmacy treatment record.

Lab results – May 20

WBC	15.5 (x 10^9/L)	Creatinine	50 (µmol/L)	Electrolytes	WNL
ANC	9.3 (x 10^9/L)	Bilirubin	12 (µmol/L)	Ca, Mg	WNL
Hgb	116 (g/L)	ALT	42 (U/L)		
Platelets	330 (x 10^9/L)	Alk Phos	72 (U/L)		

Pharmacy receives the following orders:

Oxaliplatin 98 mg IV in 250 mL D5W over 2 hours
Leucovorin 600 mg IV in 250 mL D5W over 2 hours
Fluorouracil 300 mg IV push
Fluorouracil 2400 mg continuous IV infusion over 46 hours

Calculated doses are as follows:

Oxaliplatin: 1.51 m^2 x 65 mg/m^2 = 98.2 mg
Leucovorin: 1.51 m^2 x 400 mg/m^2 = 604 mg
Fluorouracil bolus: 1.51 m^2 x 200 mg/m^2 = 302 mg
Fluorouracil infusion: 1.51 m^2 x 1600 mg/m^2 = 2416 mg

All calculated doses are within 5% of the prescribed doses and do not require clarification. The drugs can be prepared and administered as ordered. As the infusional dose of fluorouracil is less than 3000 mg, BC Cancer Pharmacy will prepare the prescribed dose individually rather than using a premixed banded dose.

Cycle 6: June 3

A.C. returns for consideration of her 6th cycle. She continues to experience Grade 3 neurotoxicity with severe impairment of her activities of daily living (ADLs). After discussion with the prescriber the decision is made to discontinue oxaliplatin. The prescriber also changes the leucovorin to IV push. According to the protocol, if oxaliplatin is omitted, leucovorin may be administered at a lower dose by IV push rather than infusion. The fluorouracil doses are maintained at the same levels as prescribed in the previous cycle. The rationale for these changes is clearly documented in the prescriber's note. After reviewing the documentation and confirming the changes are consistent with the protocol, the pharmacist proceeds with the orders as written.

Lab results – Jun 2

WBC	3.2 (x 10^9/L)	Creatinine	53 (µmol/L)	Electrolytes	WNL
ANC	2.1 (x 10^9/L)	Bilirubin	10 (µmol/L)	Ca, Mg	WNL
Hgb	110 (g/L)	ALT	41 (U/L)		
Platelets	210 (x 10^9/L)	Alk Phos	70 (U/L)		

Pharmacy receives the following orders:

Leucovorin 30 mg IV push
Fluorouracil 300 mg IV push
Fluorouracil 2400 mg continuous IV infusion over 46 hours

Calculated doses are as follows:

Leucovorin bolus: 1.51 m^2 x 20 mg/m^2 = 30.2 mg
Fluorouracil bolus: 1.51 m^2 x 200 mg/m^2 = 302 mg
Fluorouracil infusion: 1.51 m^2 x 1600 mg/m^2 = 2416 mg

All calculated doses are within 5% of the prescribed doses. The drugs can be prepared and administered as ordered. The infusional dose of 5-FU is less than 3000 mg, BC Cancer Pharmacy will prepare the prescribed dose individually rather than using a premixed banded dose.

Cycle 7: June 17

A.C. returns for consideration of her 7th cycle. She is nauseous, dehydrated and feeling "rotten". A CT scan of the liver reveals significant disease progression compared with previous CT scan of March. A.C. does not feel she has the strength to face further

treatment and agrees to a palliative care consultation. Cancer drug treatment is discontinued.