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**EDITOR’S CHOICE**

**WITHDRAWAL OF BEVACIZUMAB INDICATION IN METASTATIC BREAST CANCER**

Health Canada suspended the Notice of Compliance for the combination of Bevacizumab and PACLitaxel for the treatment of metastatic breast cancer on 25 November 2011. The impetus for this decision was due to two new clinical trials demonstrating no benefit in overall survival or improvement in disease-related symptoms with the addition of bevacizumab to PACLitaxel compared to PACLitaxel alone. [Miller et al. NEJM 2007;357:2666-76]

Bevacizumab first received the Notice of Compliance from Health Canada for the first-line treatment of HER2-negative, metastatic breast cancer in February 2009. It underwent expedited approval based on the ECOG E2100 study that demonstrated significant improvement in objective response rates (36.9% vs. 21.2%, p<0.001) and progression free survival (PFS) (11.3 mo vs. 5.8 mo, p<0.001). The approval was conditional upon further demonstration of positive results from two ongoing clinical
EDITOR’S CHOICE

trials, AVADO and RIBBON-1. [Miles et al. JCO 2010;28(20):3239-3247] [Robert et al. JCO 2011;29(10):1252-1260]

A review of these recently published trials showed a smaller magnitude of benefit in PFS (up to 2.9 months) with bevacizumab when compared to the original E2100 study. In light of no improvement in overall survival and a marginal benefit in PFS, Health Canada withdrew its approval for the indication of metastatic breast cancer, as the benefits were deemed insufficient when weighed against emerging evidence of significant toxicities. These include hypertension, myocardial infarction, heart failure, thromboembolic events, hemorrhage, delayed wound healing and gastrointestinal perforations.

Hoffmann-La Roche Ltd., the manufacturer, is in the process of removing metastatic, HER2-negative breast cancer from its official indication on the AVASTIN® product monograph. This indication has already been removed from the BC Cancer Agency Bevacizumab Cancer Drug Manual monograph. For further drug information on bevacizumab, please see the Cancer Drug Manual section of the Systemic Therapy Update.

PROVINCIAL SYSTEMIC THERAPY POLICY

NEW BCCA COMPASSIONATE ACCESS PROGRAM POLICY

A new Provincial Systemic Therapy Policy (III-45) has been developed to outline the process of the BC Cancer Agency Compassionate Access Program (CAP). This policy is based on the current application and review principles of CAP (www.bccancer.bc.ca/HPI/ChemotherapyProtocols).

Highlights from Policy III-45 include:

- Clear guidelines on when to apply for CAP
- Procedure for BCCA funding application for treatments that have undergone recurrent CAP submissions
- Note on the importance of obtaining CAP approval prior to scheduling patients for treatment
- Clear guidelines on CAP appeal process

Information related to the former Undesignated Indication approval process has been removed from the Systemic Therapy Treatments Policy (III-40). Policy III-45 can now be accessed online at: http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies.htm.

REVISED POLICY ON CETUXIMAB OBSERVATION

The Provincial Systemic Therapy Program, in collaboration with the Head & Neck and Gastrointestinal Tumour Groups, has revised the patient observation requirements post-cetuximab infusion in the Policy on Physician Coverage for Medical Emergencies During Delivery of Selected Chemotherapy Drugs (III-60). Effective 01 February 2012, the 1-hour observation period post-cetuximab infusion is only required for the first and second infusions. Observation is not required for subsequent doses if no infusion reactions occurred with the first two consecutive doses.

Approximately 90% of severe infusion reactions are associated with the first infusion of cetuximab despite the use of prophylactic antihistamines.1 Most reactions tend to be mild to moderate in severity (13%-19%
PROVINCIAL SYSTEMIC THERAPY POLICY

grades 1 and 2 infusion reactions occur on the first day of initial dose, but severe reactions have been reported at an incidence of 2%-5%. These rates appear to be consistent with those reported for other cancer drugs that also elicit severe infusion-related reactions (i.e. other monoclonal antibodies, taxanes). Because some patients may experience infusion reactions for the first time during later infusions, caution must still be exercised with every infusion.

This information has been updated on the UGIACETIR and UHNLACETRT chemotherapy protocols and pre-printed orders. Policy III-60 can be accessed online at: http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies.htm.

References:

REVISED EXTRAVASATION POLICY

The Prevention and Management of Extravasation of Chemotherapy Policy (III-20) has been updated with the following information:

- Deleted use of therapeutic heating pads – This is no longer recommended due to safety concerns. More information on this topic can be found in the January issue of the Systemic Therapy Update [Patient Safety Update: Evidence on Therapeutic Heat Application]
- Deleted fixed infusion times for vesicants – Infusion time is drug-specific and is indicated on the chemotherapy protocols and pre-printed orders.
- Changed mechanism for safety event reporting – Patient Safety & Learning System (PSLS) has replaced the Unusual Incident Form for reporting safety events.

The revised policy can be accessed online at: http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies.htm.

DRUG UPDATE

RALTITREXED DRUG SHORTAGE

Raltitrexed (TOMUDEX®) is facing a temporary supply shortage due to manufacturing issues. Hospira Healthcare Corporation is expecting a supply to be released in March 2012. Raltitrexed is indicated in the treatment of metastatic or unresectable colorectal adenocarcinoma for patients who are unable to tolerate fluorouracil or capcitabine (i.e. suspected dihydropyrimidine dehydrogenase [DPD] deficiency). There are no viable therapeutic substitutions for this indication and no alternate
supplier for this product. It is recommended that no new patients are initiated on raltitrexed at this time. Prescribers and BC hospital pharmacies will continue to collaborate to allocate the stock for patients already booked for treatment.

**REMOVAL OF CYPROTERONE FROM BENEFIT DRUG LIST**

The Genitourinary Tumour Group has recommended cyproterone to be removed from the BC Cancer Agency Benefit Drug List after reviewing its use in prostate cancer patients. Cyproterone has been used to suppress clinical flare at the initiation of therapy with a luteinizing hormone releasing hormone (LHRH) agonist. If your patient has been receiving cyproterone for the treatment of prostate cancer, this medication will no longer be funded by the BC Cancer Agency. It is strongly recommended that a non-steroidal anti-androgen (i.e. bicalutamide, flutamide) be selected as a therapeutic alternative. Historically, cyproterone had also been used in combination with diethylstilbestrol (DES) for medical castration. Its use has declined significantly over the years, and is no longer considered as the standard of practice because clinical studies have demonstrated worse survival outcomes compared to other therapeutic agents. [Prostate Cancer Trialists Collaborative Group. Lancet 2000;355:1491-1498]. Lastly, low-dose cyproterone has also been used to control vasomotor symptoms such as hot flushes. Because the BC Cancer Agency does not provide funding for supportive care medications, cyproterone is not a BCCA benefit drug for this indication.

**PATIENT SAFETY UPDATE**

**BLEOMYCIN TOXICITY IN THE TREATMENT OF TESTICULAR CANCER**

Testicular tumours are rare, but they still remain the most common solid malignancy in men between 15 to 34 years of age. Testicular cancer, regardless of stage, are treated with the goal of curing the patient. With platinum-based regimens, it is now expected that 95% of patients with early-stage testicular cancer, and up to 70% to 80% of patients with advanced cancer will survive long-term.

The BCCA Genitourinary (GU) tumour group recommends the use of bleomycin, etoposide and CISplatin (GUBEP) as the backbone systemic regimen for most of this patient population. As with any chemotherapy treatment regime, there are side effects which can range from temporary and non-life threatening to serious, life threatening events. These side effects are typically well known to health care providers and well-documented in relevant health care professional- and patient-related materials; however, life threatening and/or death events would not be commonly encountered.

Bleomycin, in particular, needs to be used with caution. Bleomycin pulmonary toxicity (BPT) can be initially subtle, but can eventually lead to death — a rare complication. While it remains difficult to predict which patients will develop this complication, a cumulative dose of greater than 450 units of bleomycin is a known significant risk factor for developing BPT. The total recommended cumulative dose of bleomycin for the GUBEP protocol at 4 cycles is 360 units.

The case study below describes an experience with a patient on the GUBEP protocol, and highlights lessons learned and recommendations for quality improvement.
**Patient Safety Update**

**Patient Case:**

An adolescent patient with intermediate risk, non-seminomatous germ cell cancer was scheduled to receive 4 cycles of GUBEP, as per recommendations from the BCCA GU Tumour Group. Risks and benefits related to the treatment plan and side effects were discussed with the patient and his family by the medical oncologist. The patient also received the patient handout for this protocol, specific drug information for each agent, and the Bleomycin Lung Toxicity Alert Card. Pre-treatment investigations included baseline blood work and baseline pulmonary function tests. Pulmonary function tests are not mandatory either prior to or during the treatment protocol, and may be ordered based on medical information and clinical decision making. There is no evidence to indicate that pulmonary function tests are predictive of risk for pulmonary toxicity.

Prior to cycle 3, the patient complained of increasing fatigue, nausea, sporadic cough and a mild shortness of breath during physical activity. On physical examination, the patient’s chest was clear. Repeat pulmonary function tests (PFTs) were ordered, although the physician noted that there did not seem to be any evidence of bleomycin toxicity at that time. The test results were normal. The patient received cycle 3 without any reported problems.

The patient was assessed by his oncologist prior to cycle 4 and complained at that time of a productive cough with white sputum. Again, chest examination and chest x-ray were clear. PFTs were again ordered prior to proceeding with day 1 of cycle 4. The oncologist reviewed the preliminary report on day 1 and reassessed the patient. The patient reported that symptoms have resolved. The patient’s diffusion capacity was 69%. Orders were given for the chemotherapy treatment to proceed.

The patient received the full treatment as ordered, including all doses of bleomycin. The day after the last dose of bleomycin was given, the patient phoned the Cancer Centre with symptoms of cough and chest tightness. The patient was assessed and admitted to the hospital.

Over the course of several weeks, the patient’s symptoms continued to worsen and ultimately resulted in a transfer to an intensive care unit. Despite maximum medical intervention, the patient passed away one month following completion of his treatment regimen. No specific etiology was found outside of the systemic therapy, and the most likely cause was felt to be complications related to bleomycin toxicity.

**Lessons Learned:**

Pulmonary toxicity is a very real and potentially fatal complication of bleomycin treatment. Assessment of respiratory function during bleomycin treatments must be comprehensive, specific and ongoing. Clinical assessments and patient self-reporting of symptoms must take into consideration particular patient characteristics. Clinicians must have a comprehensive understanding of adolescent perspectives regarding their health and symptom reporting.

Unfortunately, few published guidelines exist for the use of repeat PFTs to guide therapeutic decisions. There remains a clear need to have more comprehensive medical management guidelines for respiratory function when patients are on treatment with bleomycin. It is challenging for health care professionals to decide when to hold elements of curative treatment in the face of subtle symptoms.
**PATIENT SAFETY UPDATE**

Health care providers must ensure there is complete and systematic assessment for all patients throughout chemotherapy treatments with mindfulness regarding the patient’s age and developmental stage.

Increase awareness of bleomycin toxicity and management must be exercised for all health care providers administering this treatment protocol.

The BCCA Provincial GU Tumour Group has been asked to review the evidence and practices regarding the GUBEP protocol and the use of bleomycin. This review may result in further recommendations regarding the use of pulmonary function tests as baseline/ongoing monitoring, as well as clinical assessments and patient education.

**Reference:**

**PRACTICE UPDATE**

**LEUCOVORIN ADMINISTRATION IN GI FOLFOX CHEMOTHERAPY PROTOCOLS**

The Gastrointestinal (GI) Tumour Group has confirmed that there will be no change to the BCCA administration standard of leucovorin in the advanced GI FOLFOX chemotherapy protocols. A recent review conducted by Provincial Drug Information confirms the current standard, which states:

*Infuse leucovorin 400 mg/m² IV over 2 hours (may give concurrently with oxaliplatin via Y-site). If bolus fluorouracil is delayed/omitted, leucovorin may also be delayed/omitted or reduced to 20 mg/m² IV push.*

The Provincial Drug Information review was prompted by requests to consider the reduction in leucovorin administration time. The review included a literature search and an environmental scan on the current leucovorin administration practices at cancer institutions across Canada and internationally. Results of the review showed that there was inadequate evidence to support the administration of leucovorin 400 mg/m² over less than 2 hours, or at lower doses (less than 400 mg/m²). The impact of such changes to the modulation of fluorouracil’s activity is unknown. Of the ten Canadian cancer centres surveyed, all except one recommended the same leucovorin administration practice as the BCCA. Until further studies are available, the GI Tumour Group continues to support...
the current leucovorin administration standard as outlined in the BCCA GI chemotherapy protocols.

NEW STANDARDS AND COMPETENCIES FOR CANCER CHEMOTHERAPY NURSING PRACTICE IN CANADA

The Canadian Association of Nurses in Oncology (CANO/ACIO) is the national specialty organization supporting Canadian nurses to “promote and develop excellence in oncology nursing practice, education, research and leadership”. In response to the results of membership consultation, CANO began work on the National Strategy for Chemotherapy Administration, a special initiative to establish national chemotherapy standards, competencies and educational resources for Canadian oncology nurses. The following vision statement guided the work of this national initiative:

“Every patient across Canada, regardless of geography, receives chemotherapy treatment and care from oncology nurses who meet a predetermined standard of practice through a comprehensive education program designed to ensure ongoing competency”.

Released in September 2011, the CANO/ACIO Chemotherapy Nursing Practice Standards and Competencies address four key areas:

1. **Standard A: Accountability for Cancer Chemotherapy Nursing Practice and Care in Canada by Registered Nurses**
   This standard includes descriptions of competent chemotherapy practice required for comprehensive health assessment, supportive and therapeutic relationships, management of cancer symptoms and treatment side effects, teaching and coaching, facilitating continuity of care and navigating the health care system, decision-making and advocacy, and professional practice and leadership.

2. **Standard B: Quality Practice Environment for Optimal Cancer Chemotherapy Nursing Practice**
   This standard recognizes the need for organizational systems, policies, procedures and processes, and continuity of care to support safe and effective chemotherapy nursing practice.

3. **Standard C: Educational Requirements for Developing Competence in Cancer Chemotherapy**
   This standard outlines the educational program and evaluation criteria to prepare nurses to competently provide chemotherapy administration and care.

4. **Standard D: Cancer Chemotherapy Continuing Competence Program**.
   This standard describes the requirements for an annual continuing competence program, including identification of learning needs, development of learning plans, and a reporting strategy.

Detailed information about the National Strategy for Chemotherapy Administration and the Standards and Competencies for Cancer Chemotherapy Nursing Practice is available on the CANO website at: [http://www.cano-acio.ca/national_chemotherapy_administration_standards](http://www.cano-acio.ca/national_chemotherapy_administration_standards). The resources include the full standards and competencies document, Toolkit and PowerPoint presentation to assist nurses and organizations to implement the standards in practice, education and leadership.
**NURSING UPDATE**

The BC Cancer Agency supports the CANO Standards and Competencies for Cancer Chemotherapy Nursing Practice, and their implementation in practice, education, and a quality practice environment. For questions about the standards and competencies, and their support for your practice, please contact Karen Janes, Regional Professional Practice Leader, Nursing, at kjanes@bccancer.bc.ca. Stay tuned for further updates in the Systemic Therapy Update!

**Reference:**


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**EDUCATION UPDATE**

**UPCOMING CONFERENCES & EDUCATION PROGRAMS**

**12th Annual Canadian Oncology Winter Conference:**

Date: February 23-26, 2012  
Location: Sun Peaks Resort, Sun Peaks, BC  
Registration Deadline: None specified  
Website: [http://www.cowc.ca/index.html](http://www.cowc.ca/index.html)

Educational objectives include: (1) use of biological agents and chemotherapy through case study workshop, (2) emerging roles of biological agents for hematology and medical oncology, (3) combining biological agents with chemotherapy as targeted approach to treatment, and (4) working towards personalized medicine in oncology.

**13th International Symposium on Oncology Pharmacy Practice (ISOPP XIII):**

Date: May 9-11, 2012  
Location: Melbourne, Australia  
Registration Deadline: None specified  
Website: [http://www.isoppxiii.org/index.asp?IntCatId=14](http://www.isoppxiii.org/index.asp?IntCatId=14)

Members of the Canadian Association of Pharmacy in Oncology (CAPHo) may apply for an ISOPP Travel Grant via the “Member Award & Grant Details” link on the CAPHo member access page ([http://www.capho.org/user/login](http://www.capho.org/user/login)).

**Oncology Basics:**

Oncology Basics is a self-directed, accredited educational program that is available to members of the Canadian Association of Pharmacy in Oncology (CAPHo). Effective 01 February 2012, the program can be accessed on the CAPHo website at: [www.capho.org/education-resources/online-](http://www.capho.org/education-resources/online-).
**EDUCATION UPDATE**


The program was adapted by CAPhO in response to a 2009 educational needs survey that showed a strong need for education that focuses on the fundamental concepts of cancer treatment and chemotherapy. While the program is designed for Pharmacy practitioners, it may also be beneficial to other health professionals. Oncology Basics is the first program in the *Oncology Practice Essentials* series that is being developed by CAPhO. Future programs will include: 1) Chemotherapy Order Review, 2) Safe Handling and Distribution, and 3) Patient Care. For future updates on the *Oncology Practice Essentials* series, please visit the CAPhO website.

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**CANCER DRUG MANUAL**

**NEW MONOGRAPHS AND PATIENT HANDOUTS**

**Denosumab Monograph, Patient Handout**, and the **Chemotherapy Preparation and Stability Chart** have been developed. Expert review was provided by Dr. Anna Tinker (GU Tumour Group) and Ms. Victoria Kletas (GU Tumour Group Pharmacist). Denosumab is indicated for the prevention of skeletal-related events from bone metastases of solid tumours. The recommended dose is 120 mg subcutaneously every 4 weeks.

Denosumab is a new monoclonal antibody that binds to rank ligand (RANKL) on the surface of osteoclasts. RANKL is a protein that promotes the breakdown of bone. Denosumab inhibits osteoclast formation, function and survival, leading to increased bone mass and strength. It is a bone-modifying agent similar to bisphosphonates.

The main side effects are fatigue, nausea and hypophosphatemia. The more serious, rare side effects include hypocalcemia, osteonecrosis of the jaw (ONJ) and cellulitis. The current management of ONJ associated with denosumab is similar to that with bisphosphonates.

Amgen Canada Inc. manufactures two formulations – XGEVA® and PROLIA®. XGEVA® is indicated for reducing the risk of skeletal-related events from bone metastases of solid tumours, while PROLIA® is indicated for the treatment of osteoporosis. They contain the same active ingredient, but differ in their concentration, dosing and indication. According to the manufacturer, XGEVA® and PROLIA® are not interchangeable. Denosumab is not currently a benefit drug of the BC Cancer Agency.

**REVISED MONOGRAPHS AND PATIENT HANDOUTS**

**Bevacizumab Monograph** has been revised with deletion of breast cancer from the Uses section (see Editor’s Choice for more details), and addition of ovarian failure to the Caution and the Fertility sections.
CANCER DRUG MANUAL

Cytarabine Monograph has been revised to include a fixed dose of 20 mg for acute myeloid leukemia to the Dosage section.

BENEFIT DRUG LIST

REVISED BENEFIT CATEGORY

The Benefit Category of “case-by-case” has been re-designated as “restricted funding” to distinguish these funded treatments from those which require Compassionate Access Program approval for exceptional circumstances.

NEW PROGRAMS

The following programs have been added to the Benefit Drug List effective 01 February 2012:

**Breast:**
- DOCEtaxel, CARBOplatin and Trastuzumab (restricted funding) as adjuvant therapy for breast cancer (UBRAJDCT)
- DOCEtaxel and Trastuzumab (class II) after FEC regimen as adjuvant therapy for breast cancer (BRAJFECDT)

**Gastrointestinal:**
- Capecitabine and Irinotecan (restricted funding) for metastatic colorectal cancer (UGICAPIRI)
- Capecitabine, Oxaliplatin and Bevacizumab (restricted funding) for metastatic colorectal cancer (UGICOXB)
- Oxaliplatin, Fluorouracil, Folinic Acid and Bevacizumab (restricted funding) for metastatic colorectal cancer (UGIFFOXB)

**Genitourinary:**
- CISplatin and Gemcitabine (restricted funding) as adjuvant therapy for urothelial carcinoma (UGUUAJP)

**Head and Neck:**
- CISplatin and Vinorelbine (class I) for palliative treatment of advanced salivary gland cancers (HNSAVNP)
- Platinum, DOXOrubicin and Cyclophosphamide (class I) for treatment of advanced salivary gland cancers (HNSAVPAC)
- Tamoxifen (class I) for treatment of recurrent/metastatic salivary gland cancers (HNSAVTAM)

**Lymphoma:**
- Gemcitabine, Dexamethasone, CISplatin and RiTUXimab (restricted funding) for lymphoma (ULYGDPR)
- Maintenance RiTUXimab (restricted funding) for indolent lymphoma (ULYRMTN)
**BENEFIT DRUG LIST**

**DELETED PROGRAMS**

- Cyproterone has been deleted from the Benefit Drug List effective 01 February 2012

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**LIST OF NEW AND REVISED PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS**

BC Cancer Agency Protocol Summaries, Provincial Pre-Printed Orders (PPPOs) and Patient Handouts are revised periodically. New, revised or deleted protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring “Compassionate Access Program” (previously Undesignated Indications Request) approval are prefixed with the letter “U”.

### NEW Protocols, PPPOs and Patient Handouts (AFFECTED DOCUMENTS ARE CHECKED):

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<td>Treatment Of Recurrent/Metastatic Salivary Gland Cancers Of The Head And Neck With Tamoxifen</td>
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### REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):

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## REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):

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WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES

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<td>Reimbursement &amp; Forms: Benefit Drug List, Class II, Compassionate Access Program</td>
<td><a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms</a></td>
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