Systemic Therapy Update

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INSIDE THIS ISSUE

EDITOR'S CHOICE

HIGHLIGHTS OF CHANGES IN PROTOCOLS AND PRE-PRINTED ORDERS

Use of Frozen Gloves has been added as an option to manage **docetaxel-induced nail and skin toxicity**. For patients treated with docetaxel 60 mg/m^2 dose or greater, patients may wear frozen gloves starting 15 minutes before docetaxel infusion until 15 minutes after end of docetaxel infusion; gloves should be changed after 45 minutes of wearing to ensure they remain cold during the entire docetexel infusion. This practice will be introduced in a phased roll-out implementation as determined by each BCCA regional centre.

Background
The reported incidence of taxane-associated nail disorders ranges from 2% to 44%, with a much higher occurrence with docetaxel than paclitaxel.[1-3] Symptoms include hyperpigmentation, orange discoloration, splinter hemorrhage, hyperkeratosis and onycholysis. The pathophysiology is unclear, but some have postulated that taxanes' antiangiogenic and inflammatory effects may play a role. Nail changes tend to resolve with drug discontinuation. However, supportive management may prevent toxicity-related drug interruption or withdrawal. The application of cold temperature induces vasoconstriction and may limit the amount of drug reaching the nail bed. In a case-control study of 45 patients, grades 1 and 2 onycholysis and cutaneous toxicity were reduced from 51% to 11% and from 59% to 27%, respectively.[1]

For a list of revised documents, see under List of Revised Protocols, Pre-Printed Orders and Patient Handouts.

References:
1. Scotté F et al. Multicenter study of a frozen glove to prevent docetaxel-induced onycholysis and cutaneous toxicity of the hand. J Clin Oncol 2005;23:4424-9.
2. Bristol-Myers Squibb. TAXOL® product onograph. Montreal, Quebec: 22 February 2010.
3. sanofi-aventis. TAXOTERE® product monograph. Laval, Quebec: 4 January 2010.

BENEFIT DRUG LIST

The following programs have been added on the benefit list effective 1 September 2010:

- **Gemcitabine** (class II) as palliative therapy for metastatic breast cancer using cisplatin and gemcitabine (BRAVGEMP)
- **Gemcitabine** (class II) and **Docetaxel** (class II) as a second or third line therapy for soft tissue sarcomas (SAAVGEMD)

DRUG UPDATE – THALIDOMIDE APPROVED IN CANADA

After years of limiting access to thalidomide via the Special Access Programme (SAP), Health Canada has recently approved thalidomide (THALOMID®) as first line treatment of patients 65 years and older with multiple myeloma, in combination with chemotherapy and steroid (i.e. melphalan and prednisone).

Background

Thalidomide was first introduced in the 1950s for relieving morning sickness and insomnia. It was quickly withdrawn from the world-wide market due to reported cases of birth defects and deaths. In 2006, the US Food and Drug Administration approved thalidomide for the treatment of patients with MM based on clinical data showing prolonged survival associated with thalidomide therapy.

How Will This Change Your Practice?

Currently, there is no BCCA funding for thalidomide. It will continue to be accessed via SAP for the next few months. Once it becomes commercially available:

- thalidomide will be accessed only via the controlled distribution administered by the RevAid® program, which currently oversees the controlled distribution of lenalidomide (REVLIMID®)
- patients currently accessing thalidomide via the Canadian Thalidomide Access Program (CANTAP) will need to pay for the drug if they have private drug plans; patients without private drug plans will continue to receive compassionate supply via the RevAid® program if public funding is not available.

For more information, contact the RevAid® program at 1-888-738-2431) or visit www.RevAid.ca.

CANCER DRUG MANUAL

Azacitidine Patient Handout has been developed to accompany the existing monograph. The most commonly reported adverse reactions are:

- hematological (thrombocytopenia, neutropenia, leucopenia)
- gastrointestinal (nausea, vomiting)
- injection site reactions (redness, pain, swelling)

Carmustine Monograph has been revised to update information about the use of topical carmustine in the treatment of mycosis fungoides. Instructions for the preparation of a topical ointment formulation have been added to the Solution Preparation and Compatibility Section.

Alemtuzumab Monograph has been revised to remove instructions related to dividing subcutaneous doses as this practice is no longer necessary with the newer more concentrated solution. The Solution Preparation and Compatibility section has also been updated.

Docetaxel Monograph and Handout have been revised to include information regarding the use of frozen glove therapy for the prevention of nail toxicity.

The Cancer Drug Manual Team would like to welcome **Leanne Joki**, to the Editorial Board as a nurse representative. Leanne is a staff nurse with the BCCA – Vancouver Centre Ambulatory Care Chemotherapy Unit. She replaces **Sarah Farnalls** (BCCA – Vancouver Centre) who stepped down from the board in June. The team would like to thank Sarah for her many contributions during her time on the Board.

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):

CODE	Protocol	PPPO	Patient Handout	Protocol Title
HNLACAFRT	☐	☐	☑	Combined Chemotherapy (Carboplatin and Fluorouracil) and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
UHNLACETRT	☐	☐	☑	Combined Cetuximab and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
UHNLADCF	☐	☐	☑	Treatment of Locally Advanced Squamous Cell Carcinoma of the Head and Neck with Docetaxel, Cisplatin and Infusional Fluorouracil
HNSAVFUP	☑	☑	☐	Treatment of Advanced Head and Neck Cancer Using Cisplatin and Fluorouracil
ULYGDPR	☑	☑	☑	Treatment of Lymphoma with Gemcitabine, Dexamethasone and Cisplatin (GDP) with Rituximab
SMAVTMZ	☐	☐	☑	Palliative Therapy for Malignant Melanoma with Brain Metastases Using Temozolomide

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAVCAP	☑	☐	☐	*Eligibility clarified*	Therapy of Metastatic Breast Cancer using Capecitabine (XELODA®)
BRAVGEMP	☑	☑	☑	*Requirement for CAP approval replaced by class II*	Palliative Therapy for Metastatic Breast Cancer Using Cisplatin and Gemcitabine

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGIAJFFOX	☐	☑	☐	*Return appointment options clarified*	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
UGIAVCETIR	☐	☑	☐	*Return appointment options clarified*	Third Line Treatment of Metastatic Colorectal Cancer Using Cetuximab in combination with Irinotecan
GICART	☑	☑	☐	*Capecitabine dosing time with radiation clarified*	Curative Combined Modality Therapy for Carcinoma of the Anal Canal using Mitomycin, Capecitabine and Radiation Therapy
GICPART	☑	☑	☐	*Capecitabine dosing time with radiation clarified*	Curative Combined Modality Therapy for Carcinoma of the Anal Canal using Cisplatin, Capecitabine and Radiation Therapy
UGIGAVCFT	☐	☑	☐	*Fluorouracil dosing clarified*	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using Cisplatin, Infusional Fluorouracil and Trastuzumab
GIGAVECF	☐	☑	☐	*Fluorouracil dosing clarified*	Palliative Therapy for Metastatic or Locally Advanced Gastric, Esophagogastric Cancer Using Epirubicin, Cisplatin and Infusional 5-Fluorouracil
UGIRAJFFOX	☐	☑	☐	*Return appointment options clarified*	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
GIRCRT	☑	☑	☐	*Capecitabine dosing time with radiation clarified*	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma using Capecitabine and Radiation Therapy
GOENDAI	☐	☑	☐	*Minor typo corrected*	Advanced Therapy for Endometrial Cancer using an Aromatase Inhibitor
GOSMCCRT	☐	☑	☐	*Aprepitant dosing revised*	Treatment of Small Cell or Neuroendocrine Carcinoma of Gynecologic System Origin using Paclitaxel, Cisplatin, Etoposide and Carboplatin with Radiation
HNAVFUP	☑	☑	☐	*Premedications clarified*	Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck Cancer Using Cisplatin and Fluorouracil
HNAVPE	☐	☑	☐	*Premedications clarified*	Treatment for Intensive Cisplatin and Etoposide Chemotherapy for Recurrent and Metastatic Head and Neck Cancer
UHNAVPD	☐	☑	☐	*Premedications clarified*	Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Cisplatin and Docetaxel
UHNLADCF	☑	☐	☐	*Protocol title clarified*	Treatment of Locally Advanced Squamous Cell Carcinoma of the Head and Neck with Docetaxel, Cisplatin and Infusional Fluorouracil
HNNAVFUP	☑	☑	☐	*Premedications clarified*	Treatment for Advanced Nasopharyngeal Cancer of the Head and Neck using Cisplatin and Fluorouracil

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
HNNAVGEM	☑	☐	☐	*Treatment duration clarified*	Treatment of Loco-regionally Recurrent/Metastatic Nasopharyngeal Cancer Not Amenable for Local Curative Therapy with Gemcitabine
UMYBORTEZ	☐	☑	☐	*Platelet value clarified in dose modification section*	Treatment of Multiple Myeloma using Bortezomib with Dexamethasone
SAAVGEMD	☑	☑	☐	*Requirement for CAP approval replaced by class II*	Second or Third Line Therapy for Soft Tissue Sarcomas using Gemcitabine and Docetaxel

REVISED PROTOCOLS AND PPPOS RELATED TO USE OF FROZEN GLOVES FOR DOCETAXEL TOXICITY

CODE	Protocol Title
BRAJDAC	Adjuvant Therapy for Breast Cancer using Cyclophosphamide, Doxorubicin and Docetaxel
BRAJDC	Adjuvant Therapy for Breast Cancer Using Docetaxel and Cyclophosphamide
UBRAJDCT	Adjuvant Therapy for Breast Cancer Using Docetaxel, Carboplatin and Trastuzumab
BRAJDTFEC	Adjuvant Therapy for Breast Cancer Using Docetaxel and Trastuzumab, and Fluorouracil, Epirubicin and Cyclophosphamide
BRAJFECD	Adjuvant Therapy for Breast Cancer Using Fluorouracil, Epirubicin and Cyclophosphamide
BRAVDCAP	Palliative Therapy for Metastatic Breast Cancer Using Docetaxel and Capecitabine
BRAVDOC	Palliative therapy for metastatic breast cancer using Docetaxel
BRAVGEMD	Palliative Therapy for Metastatic Breast Cancer using Gemcitabine and Docetaxel
BRAVTRAD	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab and Docetaxel as First-Line Treatment for Advanced Breast Cancer
BRLAACD	Treatment of Locally Advanced Breast Cancer using Doxorubicin and Cyclophosphamide followed by Docetaxel
BRLAACDT	Treatment of Locally Advanced Breast Cancer using Doxorubicin and Cyclophosphamide followed by Docetaxel and Trastuzumab
UGIGDCF	Palliative Treatment of Metastatic or Locally Advanced Gastric, Esophagogastric Junction, or Esophageal Adenocarcinoma using with Docetaxel, Cisplatin and Infusional Fluorouracil
GOCXCAD	Treatment of Advanced/Recurrent Non-Small Cell Cancer of the Cervix with Carboplatin and Docetaxel in Ambulatory Care Settings
GOENDCAD	Treatment of Primarily Advanced or Recurrent Endometrial Cancer using Carboplatin and Docetaxel

CODE	Protocol Title
GOOVCADM	Primary Treatment of Invasive Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer, with no Visible Residual Tumour (Moderate-High Risk) Using Carboplatin and Docetaxel
GOOVCADR	Second Line Treatment Using Docetaxel and Carboplatin for Epithelial Ovarian Cancer Relapsing after Primary Treatment
GOOVCADX	Treatment of Visible Residual (Extreme Risk) Invasive Epithelial Ovarian Cancer Using Carboplatin and Docetaxel
GOOVDOC	Treatment Of Progressive, Platinum-Refractory Epithelial Ovarian Carcinoma, Primary Peritoneal Carcinoma Or Fallopian Tube Carcinoma Using Docetaxel
GOSADG	Treatment of Uterine Sarcoma Cancer using Docetaxel and Gemcitabine
GUPDOC	Palliative Therapy for Metastatic Hormone Refractory Prostate Cancer Using Docetaxel
UHNAVDOC	Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Docetaxel
UHNAVPD	Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Cisplatin and Docetaxel
UHNLADCF	Palliative Treatment of Metastatic or Locally Advanced Squamous Cell Carcinoma of the Head and Neck with Docetaxel, Cisplatin and Infusional Fluorouracil
LUAVDC	First-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Cisplatin and Docetaxel
LUAVDOC	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Docetaxel
SAAVGEMD	Second or Third Line Therapy for Soft Tissue Sarcomas using Gemcitabine and Docetaxel

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	www.bccancer.bc.ca
REIMBURSEMENT AND FORMS: BENEFIT DRUG LIST, CLASS II, BC CANCER AGENCY COMPASSIONATE ACCESS PROGRAM	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms
CANCER DRUG MANUAL	www.bccancer.bc.ca/cdm
CANCER MANAGEMENT GUIDELINES	www.bccancer.bc.ca/CaMgmtGuidelines
CANCER CHEMOTHERAPY PROTOCOLS, PRE-PRINTED ORDERS, PROTOCOL PATIENT HANDOUTS	www.bccancer.bc.ca/ChemoProtocols
SYSTEMIC THERAPY PROGRAM POLICIES	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies
SYSTEMIC THERAPY UPDATE	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate

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