

Systemic Therapy Update



BC Cancer Agency

CARE + RESEARCH

An agency of the Provincial Health Services Authority

July 2010

Volume 13, Number 7

For health professionals who care for cancer patients
Available online at www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate

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EDITOR'S CHOICE

HIGHLIGHTS OF NEW AND REVISED PROTOCOLS

Several **new** agents or indications have been added to the benefit list, including:

- **Azacitidine** for intermediate-2 and high risk myelodysplastic syndrome
- **Degarelix** for advanced prostate cancer
- **Temozolomide** for melanoma with brain metastases.

For more information about Azacitidine and Degarelix, see under Drug Update in this issue.

The **Head and Neck Tumour Group** has reorganized the protocols so that the protocol codes can better reflect the tumour subsites and treatment intents.

The **Lung Tumour Group** has introduced four more patient information handouts for the chemotherapy regimens. This means that nearly two-thirds of all lung chemotherapy protocols now have accompanying information for the patients.

DRUG UPDATE

Azacitidine, a pyrimidine analogue used for myelodysplastic syndrome (MDS), is a new program requested for funding for the fiscal year 2010/11 (see May 2010 issue of [Systemic Therapy Update](#)). Starting 1 July 2010, the BCCA will fund azacitidine 75 mg/m² given subcutaneously for 7 consecutive days for transplant ineligible patients with intermediate-2 or high risk MDS according to the International Prognostic Scoring System (protocol ULKMDSA). This is based on clinical evidence of improved overall survival compared to supportive care.

The manufacturer's Vidaza® Access Program is closed to registration for new patients starting 1 July 2010 (tel: 1-877-384-3292, Vidaza@assistprogram.com). For patients who have been accessing azacitidine via this program:

1. BCCA will cover for patients starting 1 July 2010 if:
 - their azacitidine treatment fulfills the BCCA criteria (see above),
 - the patients were registered with the Vidaza® Access Program on or after 1 April 2010, and
 - the requests have been approved by the BCCA Compassionate Access Program (CAP).
2. Vidaza® Access Program will continue to cover for patients if:
 - their azacitidine treatment does not fulfill the BCCA criteria, or
 - the patients were registered with the Vidaza® Access Program prior to 1 April 2010.

Degarelix is a Luteinizing Hormone Releasing Hormone (LHRH) antagonist used for the treatment of advanced prostate cancer. It suppresses testosterone production to castrate level similar to that seen with the LHRH agonists. However, it has the advantage of inducing testosterone suppression at a faster rate and without the initial surge in testosterone production (“flare”) associated with LHRH agonists. Currently, degarelix is available as a monthly subcutaneous depot injection.

Aminolevulinic acid and **methyl aminolevulinat**e are topical photosensitizing agents used in combination with photodynamic therapy (PDT) to treat actinic keratoses and other skin cancers (e.g., squamous cell carcinoma, basal cell carcinoma). Following topical application, photoactive porphyrins (PAPs) accumulate in the target lesions and form singlet molecular oxygen when exposed to light, causing local cytotoxic effects on the light-exposed lesions.

BENEFIT DRUG LIST

The following treatment programs have been added to the benefit drug list effective 1 July 2010:

- **Aminolevulinic acid** topical solution 20% and **methyl aminolevulinat**e cream (both class I) as topical therapy for skin cancer with PDT (photodynamic therapy) (SMPDT)
- **Azacitidine** (case-by-case) as therapy of myelodysplastic syndrome with International Prognostic Scoring System (IPSS) intermediate-2 and high risk (ULKMDSA)
- **Degarelix** (class I) as therapy for prostate cancer using LHRH antagonist degarelix (GUPLHRHA)
- **Temozolomide** (class II) as palliative therapy for malignant melanoma with brain metastases when other treatment modalities are not advisable (SMAVTMZ)

CANCER DRUG MANUAL

Tocilizumab Interim Monograph has been developed. Tocilizumab is a new humanized anti-human IL-6 antibody supplied for compassionate use in the treatment of multi-centric Castleman disease, an

uncommon lymphoproliferative disorder. It is dosed at 4-8 mg/kg IV every two weeks. The most commonly reported adverse reactions are upper respiratory tract infections, nasopharyngitis, headache, hypertension, and increased ALT. Other highlights of the document include:

- Infusion reactions can occur rarely. The most frequently reported event occurring during infusion was hypertension. Clinically significant reactions requiring treatment discontinuation were reported in less than 1%.
- Gastrointestinal perforation has been reported, primarily as a complication of diverticulitis. New abdominal symptoms should be evaluated promptly.
- Multiple sclerosis and chronic inflammatory demyelinating polyneuropathy have been rarely reported in studies.

Tocilizumab has now been added to the **Chemotherapy Preparation and Stability Chart**.

Alemtuzumab Patient Handout has been revised to remove all references to the ampoule formulation, as alemtuzumab is now available as a vial.

Bevacizumab Monograph has been revised to include glioblastoma (brain tumour) as a new Health Canada indication.

Cetuximab has been revised to include normal saline as a flushing solution in the **Chemotherapy Preparation and Stability Chart**.

MEDICATION SAFETY – MEDICATION INCIDENTS INVOLVING CANCER CHEMOTHERAPY AGENTS

The Institute on Safe Medication Practices (ISMP) of Canada has recently published an overview of chemotherapy-related incidents. The overview has found that the narrative information from voluntary incident reports is an essential factor for improving safety procedures in chemotherapy delivery. This finding effectively reinforces the importance for all healthcare professionals to voluntarily report medication errors.

ISMP Canada further analyzed over 450 chemotherapy-related incidents reported by institutions across the country during 2002-2009. Seven main themes were revealed, each pertaining to a process within the system of providing cancer chemotherapy. Of these seven themes, notable examples include: administration of medication, dispensing, monitoring, and prescribing.

Within these main themes, a few of the subthemes (specific errors) reported were: incorrect dose, incorrect rate, incorrect medication, omission of dose, and incorrect patient. Recognizing subtheme trends and identifying key contributing factors will spotlight opportunities for system improvement and safeguards, such as eliminating the use of dangerous abbreviations. While these findings are an impetus for changing the way we provide chemotherapy to our patients, more work is needed to identify preferred practices within our medication-use system.

This ISMP Canada Safety Bulletin, March 16, 2010 (Volume 10, number 1), can be found at: <http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2010-01-CancerChemotherapyAgents.pdf>

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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):

CODE	Protocol	PPPO	Patient Handout	Protocol Title
GUPLHRHA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Therapy for Prostate Cancer Using LHRH Antagonist Degarelix
UHNAVDOC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Docetaxel
HNAVP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Palliative Chemotherapy for Advanced Head and Neck Squamous Cell Carcinoma with Weekly Cisplatin
UHNAVDP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Cisplatin and Docetaxel
UHNLADCF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Palliative Treatment of Metastatic or Locally Advanced Squamous Cell Carcinoma of the Head and Neck with Docetaxel, Cisplatin and Infusional Fluorouracil
UHNNAVCAP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment Of Recurrent Or Metastatic Nasopharyngeal Cancer With Capecitabine
UHNNAVPC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma with Carboplatin and Paclitaxel
ULKMSDA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Therapy of Myelodysplastic Syndrome using Azacitidine
LUAVDC	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment of Advanced Non-Small Cell Lung Cancer with Cisplatin and Docetaxel
LUAVDOC	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Docetaxel
LUMMVIN	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment of Malignant Mesothelioma with Vinorelbine
LUSCCAV	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment of Extensive Small Cell Lung Cancer (SCLC) with Cyclophosphamide, Doxorubicin and Vincristine (CAV)
SMAVTMZ	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Palliative Therapy for Malignant Melanoma with Brain Metastases
SMPDT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Topical Therapy for Skin Cancer with PDT (Photodynamic Therapy)

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BMTMM0301	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Renal dose adjustment revised, reference added</i>	Conditioning Therapy for Autologous Stem Cell Transplant using high dose Melphalan in the Treatment of Multiple Myeloma
GIAVPG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>References added</i>	First-line Palliative Chemotherapy for Advanced Gallbladder Cancer and Cholangiocarcinoma using Gemcitabine and Cisplatin
GIOCTLAR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Symptomatic Management of Functional Carcinoid and Neuroendocrine Tumors of the GI Tract Using Octreotide
HNAMIRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code revised</i>	Radioprotection in Head and Neck Radiation using Amifostine
HNAVFUP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Emetogenic potential revised in protocol and aprepitant added to Premedications</i>	Treatment of Advanced Head and Neck Cancer Using Cisplatin and Fluorouracil
HNAVGEM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code and contact physician revised</i>	Treatment of Loco-regionally Recurrent/Metastatic Nasopharyngeal Cancer not Amenable for Local Curative Therapy with Gemcitabine
HNAVM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Replacing HNM</i>	Treatment of Head and Neck Cancer Using Methotrexate as Standard Therapy
HNAVPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Replacing HNPE</i>	Intensive Cisplatin and Etoposide Chemotherapy for Recurrent and Metastatic Head and Neck Cancer
HNCAFRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code and contact physician revised, eligibility and bloodwork clarified</i>	Combined Chemotherapy (Carboplatin and Fluorouracil) and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
HNLACAFRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Replacing HNCAFRT</i>	Combined Chemotherapy (Carboplatin and Fluorouracil) and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
UHNLACETRTR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code and contact physician revised, eligibility tests clarified, post-infusion observation clarified, reference updated</i>	Combined Cetuximab and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
HNM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code and contact physician revised</i>	Treatment of Head and Neck Cancer Using Methotrexate as Standard Therapy
HNNAVGEM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Replacing HNAVGEM</i>	Treatment of Loco-regionally Recurrent/Metastatic Nasopharyngeal Cancer not Amenable for Local Curative Therapy with Gemcitabine

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
HNOTAMIRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Replacing HNAMIRT</i>	Radioprotection in Head and Neck Radiation using Amifostine
HNOTTSH	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Replacing HNTSH</i>	Radioiodine Imaging and Treatment in Patients with Thyroid Cancer Using Thyrotropin Alpha
HNPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code and contact physician revised, emetogenic potential revised, aprepitant added, reference added</i>	Intensive Cisplatin and Etoposide Chemotherapy for Recurrent and Metastatic Head and Neck Cancer
HNTSH	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol code and contact physician revised</i>	Radioiodine Imaging and Treatment in Patients with Thyroid Cancer Using Thyrotropin Alpha
LUAJNP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected in renal dosing adjustment</i>	Adjuvant Cisplatin and Vinorelbine Following Resection of Non-Small Cell Lung Cancer
LUSCCAV	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Number of treatment cycles clarified</i>	Treatment of Extensive Small Cell Lung Cancer (SCLC) with Cyclophosphamide, Doxorubicin and Vincristine (CAV)
LYCARTOP	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Refill instructions clarified</i>	Topical Carmustine in Cutaneous T-cell Lymphoma
LYCHOPR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Information on peripheral lymphocyte count added</i>	Treatment of Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine, Prednisone and Rituximab.
LYCODOXMR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility revised</i>	Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab
ULYRICE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Information on peripheral lymphocyte count added</i>	Treatment of Advanced Stage Large B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, Carboplatin, Etoposide and Rituximab
UMYBORTEZ	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Administration route of dexamethasone clarified</i>	Treatment of Multiple Myeloma with Bortezomib and Dexamethasone
UMYMPBOR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected in lab section</i>	Treatment of Multiple Myeloma using Melphalan, Prednisone and Weekly Bortezomib
SMDTIC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Caution to protect from light clarified</i>	Palliative Therapy for Metastatic Malignant Melanoma Using High Dose Dacarbazine (DTIC)

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
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