



For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

GENERIC IMATINIB

Two generic forms of imatinib have recently been approved by Health Canada. These products have been shown to have equivalent bioavailability to GLEEVEC[®], with similar serum imatinib levels and areas under the curve (AUC) after oral ingestion.^{1,2} Therefore, they are expected to have similar efficacy to GLEEVEC[®]. The Leukemia/BMT Program of BC, the BCCA Sarcoma Tumour Group, and the Pediatric Oncology/Hematology/BMT Program endorse the use of these generic products when imatinib is prescribed. Effective October 1st, pharmacy purchasers should begin switching to Teva-Imatinib as they deplete their GLEEVEC[®] supply.

For at least the first 12 months following this policy change, patients receiving generic imatinib for chronic myeloid leukemia should have 3-monthly peripheral blood quantitative PCR for BCR/ABL transcripts analysis, even if they have stable major molecular response (see revised LKCMMLI protocol). The need to continue this monitoring practice will be reviewed by the Leukemia/BMT Program of BC after the first 12 months. There will be no change in disease monitoring for patients receiving imatinib for gastrointestinal stromal tumours (BCCA protocols SAAJGI, SAAVGI and SAAVGIDD). Physicians will soon receive communication outlining the switch to generic imatinib from the Tumour Groups.

There have been no reports of different efficacy related to the generic imatinib formulations that are approved for use in Canada^{1,2} or in the European Union.³⁻⁵ Anecdotal concerns of reduced efficacies have been limited to different generic versions of imatinib used in several Arab countries⁶⁻¹⁰ and Iran.¹¹ They involved either very small numbers of patients (total n=5)⁶⁻⁹ or reported contradictory findings (90% response rate¹¹ vs. 33% relapse rate¹⁰). Unlike the generic formulations of imatinib approved in Canada, it

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is unclear whether those used in these cases have been shown to be bioequivalent to GLEEVEC®.⁶⁻¹²

Also, there is no evidence that different polymorphic forms of imatinib products can lead to different clinical outcomes. Both the β -crystal form (GLEEVEC®) and the α -crystal form (generic imatinib)¹ are highly water soluble³⁻⁵ and readily absorbed orally, as reflected by their equivalent serum imatinib levels and AUC.¹⁻⁵

References:

1. Teva Canada Ltd. TEVA-IMATINIB® product monograph. Toronto, Ontario; 28 March 2013.
2. Apotex Inc. APO-® product monograph. Toronto, Ontario; 4 June 2013.
3. European Medicines Agency. Assessment Report - Imatinib Teva. London, United Kingdom; 18 October 2012.
4. European Medicines Agency. Assessment Report - Imatinib Actavis. London, United Kingdom; 21 February 2013.
5. European Medicines Agency. Assessment Report - Imatinib Accord. London, United Kingdom; 25 April 2013.
6. Asfour IA, Elshazly SA. Changing therapy from Glivec to a "copy" imatinib results in a worsening of chronic myeloid leukemia disease status: Two case reports. *Case J* 2009;2;9342.
7. Goubran HA. Failure of a non-authorized copy product to maintain response achieved with imatinib in a patient with chronic phase chronic myeloid leukemia: A case report. *J Med Case Rep* 2009;3;7112.
8. Chouffai Z. Hematologic relapse after 2 years on a non-authorized copy version of imatinib in a patient with chronic myeloid leukemia in chronic phase: a case report. *Case Rep Oncol* 2010;3:272-276.
9. Mattar M. Failure of copy Imatib (CIPLA, India) to maintain hematologic and cytogenetic responses in chronic myeloid leukemia in chronic phase. *Int J Hematol* 2010;91(1):104-106.
10. Alwan A, Alshami A, Hatim A, et al. Impact of switching therapy from imatinib mesylate to generic copy of imatinib on hematologic response in patients with chronic phase chronic myeloid leukemia: single center study. Presented at the Congress of the European Hematology Association; 11 June 2011; London, United Kingdom. Abstract 1219.
11. Razmkhah F, Razavi M, Zaker F, et al. Hematologic and molecular responses to generic imatinib in patients with chronic myeloid leukemia. *Lab Med* 2010;41(9):547-550.
12. Gogtay J, Chahchad S, Jadhav S, et al. Response to the case report by Mattar: Generic Imatinib (Imatib, Cipla) in a patient with chronic myeloid leukemia in chronic phase. *Int J Hematol* 2010;92(5):772-773.

NEW PROGRAMS

Gastrointestinal:

Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Carcinomatosis from Limited Advanced Colorectal and Appendiceal Carcinomas Using Oxaliplatin and Fluorouracil (GIHIPEC)

– This regimen is indicated for select patients with advanced mucinous or non-mucinous appendiceal or colorectal carcinomas limited to the peritoneum, who demonstrate a good performance status. The cytoreductive debulking surgery (CRS) and HIPEC are carried out at Vancouver General Hospital under the supervision of Surgical Oncology with participation from Medical Oncology. For patients with mucinous carcinomatosis secondary to appendiceal tumours (pseudomyxoma peritonei), CRS plus HIPEC results in a 5-year overall survival (OS) of 74%, compared to 40% with CRS alone. [Chua TC et al. *JCO* 2012;30(20):2449-56]. For patients with low-volume carcinomatosis secondary to colorectal cancer, there is randomized controlled trial evidence showing benefit with CRS plus HIPEC using mitomycin C followed by adjuvant-intent fluorouracil, compared to fluorouracil alone (5-year disease-specific survival 20% vs. 9%). [Verwaal VJ et al. *Ann Surg Oncol* 2008;15(9):2426-32] In a more recent multicenter cohort study evaluating HIPEC using oxaliplatin and neoadjuvant and/or adjuvant systemic therapy with oxaliplatin/irinotecan-containing regimens, 5-year OS of 27% to 51% and 5-year disease-free survival (DFS) of 10% were achieved. [Elias D et al. *JCO* 2010;28 (1):63-8] All eligible cases shall be presented and reviewed at the BCCA multidisciplinary GI conference for approval.

NURSING UPDATE

UPDATED BCCA SYMPTOM MANAGEMENT GUIDELINES

All [BCCA Symptom Management Guidelines](#) (SMGs) have been recently updated to reflect current evidence and practice. Key changes are as follows:

- Updates reflect the latest version of the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) scale (version 4.03).
- Recommendations have been made more succinct.
- Repetitive recommendations have been deleted throughout grade levels.
- Addition of a *Referral and Resources* section.

Use of these guidelines can improve consistency in care amongst practitioners and patient outcomes. For questions about the updated guidelines, please contact the Education Resource Nurse Team at nursinged@bccancer.bc.ca or 604-877-6000 (Ext. 672638).

CONTINUING PROFESSIONAL DEVELOPMENT

FAMILY PRACTICE ONCOLOGY CME DAY 2013

Date: 02 November 2013
Location: BC Cancer Agency Research Centre, Vancouver, BC
Registration: Now through November 2, 2013
Website: www.fpon.ca

The Family Practice Oncology CME Day is intended to enhance population based cancer care by offering family physicians, general practitioners in oncology (GPOs), nurses and pharmacists this education opportunity. The event addresses topics most frequently requested by family physicians, and provides updates and insights on new resources for primary care. Topics will include cancer screening, leukemias, spinal cord compression, and more. There will also be small group workshops on breast cancer, colorectal cancer, and pain & symptom management. Please visit www.fpon.ca for full details and registration.

The event meets the accreditation criteria of the College of Family Physicians of Canada and has been accredited by the BC Chapter for up to 5 Mainpro-M1 credits.

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Pazopanib Monograph:

- *Caution and Side Effect sections* – updated information about hepatic toxicity and liver function test monitoring as per Health Canada warning
- *Interactions table* – added simvastatin interaction (increased risk of ALT elevations)

BENEFIT DRUG LIST

NEW PROGRAMS

The following program has been added to the Benefit Drug List effective 01 October 2013:

Protocol Title	Protocol Code	Benefit Status
Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Carcinomatosis from Limited Advanced Colorectal and Appendiceal Carcinomas Using Oxaliplatin and Fluorouracil (5-FU)	GIHIPEC	Class II

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
GIHIPEC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Carcinomatosis from Limited Advanced Colorectal and Appendiceal Carcinomas Using Oxaliplatin and Fluorouracil (5-FU)
HNAVPE	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment for Intensive CISplatin and Etoposide Chemotherapy for Recurrent and Metastatic Head and Neck Cancer (Squamous Cell Carcinoma)
HNNAVPE	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment of Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Etoposide

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dilution clarified, TALLman lettering and lower case drug name formatted</i>	Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide followed by PACLitaxel
BRAJACTG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dilution clarified, TALLman lettering and lower case drug name formatted</i>	Adjuvant Therapy for Breast Cancer using Dose Dense Therapy: DOXOrubicin and Cyclophosphamide followed by PACLitaxel
BRAJACTT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dilution clarified, TALLman lettering and lower case drug name formatted</i>	Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACTG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dilution clarified, TALLman lettering and lower case drug name formatted</i>	Adjuvant Therapy for Breast Cancer using Dose Dense Therapy: DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab
BRAJANAS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Hyperlink updated in Eligibility</i>	Adjuvant Therapy for Breast Cancer using Anastrozole in Postmenopausal Women
BRAJEXE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Hyperlink updated in Eligibility</i>	Adjuvant Therapy for Breast Cancer using Exemestane in Postmenopausal Women
BRAJFCDT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dilution clarified</i>	Adjuvant Therapy for Breast Cancer using Fluorouracil, Epirubicin and Cyclophosphamide followed by DOCEtaxel and Trastuzumab
BRAJLET	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Hyperlink updated in Eligibility</i>	Adjuvant Therapy for Breast Cancer using Letrozole in Postmenopausal Women
BRAJTAM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Hyperlink updated in Eligibility</i>	Adjuvant Therapy for Breast Cancer Using Tamoxifen
BRLAACDT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dilution clarified, lower case drug name formatted</i>	Treatment of Locally Advanced Breast Cancer using DOXOrubicin and Cyclophosphamide followed by DOCEtaxel and Trastuzumab
UCNBEV	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Lower case drug name formatted; schedules of etoposide dosing, bevacizumab dosing modification and return appointments clarified</i>	Palliative Therapy for Recurrent Malignant Gliomas Using Bevacizumab With or Without Concurrent Etoposide or Lomustine
GICART	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment schedule clarified</i>	Combined Modality Therapy for Carcinoma of the Anal Canal using Mitomycin, Capecitabine and Radiation Therapy
GIENACTRT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment schedule clarified</i>	Neoadjuvant Treatment of Esophageal and Gastroesophageal Carcinomas Using CARBOplatin, PACLitaxel and Radiation Therapy
GIFFIRB	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment schedule clarified</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab
UGIGAVCCT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment schedule clarified</i>	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin, Capecitabine and Trastuzumab

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGIGAVCFT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment schedule clarified</i>	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin, Infusional Fluorouracil and Trastuzumab
GIPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>TALLman lettering and lower case drug name formatted, CARBOplatin diluent updated, treatment schedule clarified</i>	Palliative Therapy of Neuroendocrine Tumours using CISplatin and Etoposide
GOCXCAT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Dosing interval options revised, contact physician updated</i>	Primary Treatment of Advanced/Recurrent Non-Small Cell Cancer of the Cervix with CARBOplatin and PACLitaxel in Ambulatory Care Setting
GOENDCAT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility revised</i>	Treatment of Primary Advanced or Recurrent Endometrial Cancer using CARBOplatin and PACLitaxel
GOOVDDCAT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility revised, Day 1 Dose Modification table revised</i>	Primary Treatment of Advanced Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using CARBOplatin and Weekly PACLitaxel
GOOVIPPC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility and Exclusions revised</i>	Primary Treatment of Stage III less than or equal to 1 cm Visible Residual Invasive Epithelial Ovarian Cancer or Stage I Grade 3 or Stage II Grade 3 Papillary Serous Ovarian Cancer Using Intravenous and Intraperitoneal PACLitaxel and Intraperitoneal CARBOplatin
UGUPAZO	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Liver test monitoring updated under Laboratory Testing</i>	Palliative Therapy for Renal Cell Carcinoma Using Pazopanib
HNAVFUP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Carboplatin option added, lower case drug name formatted</i>	Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck Cancer Using Fluorouracil and Platinum
HNAVDP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Carboplatin option added</i>	Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Platinum and DOCetaxel
HNAVPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Carboplatin option and reference added, hepatic dose modification updated, lower case drug name formatted</i>	Treatment of Recurrent and Metastatic Squamous Cell Cancer with Platinum and Etoposide
HNNAVFUP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Carboplatin option added, title updated, lower case drug name formatted</i>	Treatment of Advanced Nasopharyngeal Cancer of the Head and Neck using Platinum and Fluorouracil
HNNAVPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Carboplatin option added, title and hepatic dose modification updated</i>	Treatment of Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Etoposide
LKCMLI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Monitoring parameters updated</i>	Therapy for Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia Using Imatinib

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
USMAVIPI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Ocular melanoma deleted from Exclusions, references added</i>	Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	www.bccancer.bc.ca
Systemic Therapy Update	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate
Reimbursement & Forms: Benefit Drug List, Class II, 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
CON Pharmacy Educators	http://www.bccancer.bc.ca/HPI/Pharmacy/ContactUs.htm

CONTACT INFORMATION	PHONE	FAX	EMAIL
Systemic Therapy Update Editor	604.877.6000 x 673028		sally.waignein@bccancer.bc.ca
Provincial Systemic Therapy Program	250.712.3900 x 686620		mberk@bccancer.bc.ca
To update the contact information of any CON sites, please contact:			bulletin@bccancer.bc.ca
Oncology Drug Information	604.877.6275		druginfo@bccancer.bc.ca
Education Resource Nurse	604.877.6000 x 672638		nursinged@bccancer.bc.ca
Library/Cancer Information	604.675.8003 Toll Free 888.675.8001 x 8003		requests@bccancer.bc.ca
Pharmacy Professional Practice	250. 519.5574		jkippen@bccancer.bc.ca
Nursing Professional Practice	604.877.6000 x 672623		ilundie@bccancer.bc.ca
OSCAR	888.355.0355	604.708.2051	oscar@bccancer.bc.ca
Compassionate Access Program (CAP)	604.877.6277	604.708.2026	cap_bcca@bccancer.bc.ca
Pharmacy Chemotherapy Certification	250.712.3900 x 686741		rxchemocert@bccancer.bc.ca
BCCA-Abbotsford Centre	604.851.4710 Toll Free 877.547.3777		
BCCA-Centre for the North	250.645.7300 Toll Free 888.775.7300		
BCCA-Fraser Valley Centre	604.930.2098 Toll Free 800.523.2885		
BCCA-Sindi Ahluwalia Hawkins Centre for the Southern Interior	250.712.3900 Toll Free 888.563.7773		
BCCA-Vancouver Centre	604.877.6000 Toll Free 800.663.3333		
BCCA-Vancouver Island Centre	250.519.5500 Toll Free 800.670.3322		

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