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for health professionals who care for cancer patients
Website access at <a href="http://www.bccancer.bc.ca/STUpdate/">http://www.bccancer.bc.ca/STUpdate/</a>

January 2004

#### INSIDE THIS ISSUE

Drug update – Gefitinib (Iressa®, ZD 1839)

FAX request form and IN TOUCH phone list are provided if additional information is needed.

### **DRUG UPDATE**

**Gefitinib (Iressa®, ZD 1839)** 250 mg PO per day has recently been granted conditional approval by <u>Health Canada</u> as monotherapy (third line therapy) for the treatment of patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC) who have failed prior platinum-based and docetaxel chemotherapy.

Until now, this drug has been available free of charge through the Special Access Programme (called Expanded Access Programme for this drug). Physicians needed undesignated approval from BCCA and SAP approval from Health Canada and AstraZeneca in order to use gefitinib. With the Health Canada approval, the Expanded Access Programme will no longer be available for this drug for any indications. The following interim changes have been made:

- 1. <u>Patients currently receiving gefitinib</u>: Patients will continue to receive free drug until their therapy is stopped. Physicians need to withdraw the patients from the Expanded Access Programme and then apply to the Iressa® Patient Assistance Program (IPAP).
- 2. New lung cancer patients starting gefitinib: New patients will not be reimbursed by the BCCA at the present time. Over the next four months, new patients who fit the Health Canada approved indication can apply to the IPAP and receive free drug throughout their treatment. Physicians treating these patients will still need to receive BCCA undesignated approval.

New lung cancer patients who do not fit the Health Canada approved indication will <u>not</u> be reimbursed by the IPAP or the BCCA at the present time.

3. <u>Head and Neck cancer patients</u>: New patients will <u>not</u> be reimbursed by the IPAP or the BCCA at the present time.

## Applying for Iressa® Patient Assistance Program (IPAP)

The BCCA has set up the following at the regional cancer centres (see also attached <u>flow chart</u>):

Step 1. If applicable, physicians should withdraw patients from the Expanded Access Programme by sending the completed <u>EAP Withdrawal Form</u> to the pharmacy.

- Step 2. Physicians send the completed <u>IPAP Application Form</u> and <u>New Supply Form</u> to the pharmacy, which will review and send them to the IPAP. Note that certain sections of the IPAP Application Form are not relevant to patients in BC:
  - (a) section 2, Third Party Billing information please disregard.
  - (b) section 5, Signatures patient's signature is required but not the Primary Insurance Holder's signature.

Once approved, the IPAP will send one month's supply to the hospital pharmacy.

Step 3. For further supply, fax the completed Repeat Form to the IPAP.

Relevant application forms are available from the IPAP (tel. 1-866-473-7720, fax. 1-866-706-2830). For the regional centres of the BC Cancer Agency, these forms can also be obtained from the h-drive <u>systemic</u> chemo reimbursement forms.

For more information, call the BCCA Undesignated Indication Requests at (604) 877-6277 or 1-800 633-3333 local 6277.

### **Editorial Review Board**

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Fraser Valley Centre (FVCC)	(604)-930-2098	Toll-Free 1-(800)-523-2885
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Vancouver Island Centre (VICC)	(250) 519-5500	Toll-Free 1-(800)-670-3322

# **BC CANCER AGENCY SYSTEMIC THERAPY UPDATE REQUEST FORM**

FAX (604) 877-0585

bulletin@bccancer.bc.ca

TO SUBSCRIBE: FAX OR EMAIL YOUR REQUEST OR CALL @ 877-6098 LOCAL 2247

FOR URGENT REQUESTS PLEASE CALL (604) 877-6098 LOCAL 2247

OR TOLL-FREE IN BC 1-800-663-3333 LOCAL 2247

PLEASE FEEL FREE TO MAKE COPIES FOR YOUR COLLEAGUES

I WOULD PREFER TO RECEIVE THIS INFORMATION VIA:

☐ E-mail (Word 6.0)		@			
☐ Fax	( )	Attn:			
***Items have been hyperlinked for easy access at regional cancer centres***					
Gefitinib (Iressa®) Patient Assistance Procedures					
		Shortcut to Gefitinib (Iressa) Forms.lnk			
Undesignated Inc	dication Applicatio	on Form			
Expanded Assistance Programme (EAP) Withdrawal Form					
Iressa® Patient Assistance Program (IPAP) Application Form					
Iressa® Patient Assistance Program (IPAP) New Supply Form					
Iressa® Patient Assistance Program (IPAP) Repeat Form					