ONE YEAR LATER
Are We Making Progress?

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Some cancer drugs make the difference between life and death for selected patients. Last year's CACC Report Card focused on patients' access to 24 of those drugs.[1] The Report Card also described federal mechanisms that make them available and outlined the different provincial approval and funding structures.

The Report Card found marked variability in access to cancer drugs from province to province. It also highlighted why, among the major modalities of cancer treatment, this form of therapy is the least conforming to the guiding principles of the Canada Health Act. Coverage of the newer drugs provided in hospital-based clinics is not accessible, universal, portable, comprehensive or publicly administered.

This year the CACC Report Card surveys the progress made since last year and again summarizes changes in access to individual cancer drugs within the public system. As well, it describes a new trend in access: the development of public and private initiatives aimed at providing new drugs to cancer patients on a pay-as-you-go basis. The Report touches on the evolving nation-wide initiatives that may improve the complex and highly variable processes by which they are made available, or not, to Canadian patients who need them.

Methodology

Referring to the same 24 cancer drugs reviewed last year, CACC surveyed medical oncology specialists and oncology pharmacy experts in each province – the professionals most familiar with what is actually available – to determine the current funding status and availability of the drugs as of December 31, 2006.

Data were compiled from multiple sources, including public information on web sites and interviews with health professionals in every province. The researchers frequently encountered lack of clarity, conflicting data or absence of data in most provinces, particularly in those where no formal review/approval mechanism was in place. In such cases the research was expanded until several sources were able to confirm the facts as presented, or, in the case of Quebec, until several sources confirmed that access for some drugs was too variable to be tracked.

Private pay options were investigated in each province. Parenteral drugs (given intravenously) paid for by the patient or a third party, but given within the public system were categorized as A and those given through private infusion clinics are category B. CACC also investigated the current and planned distribution of private infusion clinics for cancer across the country.

This information is presented in a master table and then an abbreviated summary was created, by province, of key approvals and events related to cancer drug access in 2006.

Definitions of Limited Access

The definitions regarding the type and degree of access are listed at the bottom of Table 1. Last year the designation "L" described a range of limited access situations. This year, rather than combine all limitations in this one group, limited access was divided into four subgroups to differentiate degrees of access more precisely.

L1 Drugs are publicly funded for all patients with disease-specific indications. Requires case-by-case application/description, reflecting the gate-keeping role. In theory, any eligible patient meeting the criteria would receive the drug, although it cannot be asserted that every patient who would benefit from the drug would meet the criteria.

L2 Drugs are publicly funded only for subgroups of patients, e.g., those who are over 65 years of age, or receiving social assistance, as covered through several pharmacare plans.

L3 Drugs are publicly funded but available at only some provincial cancer centres/hospitals but not others. This category can reflect variability in the

adoption and use of new drugs when there is lack of a province-wide process for evaluating or recommending new cancer drugs, or variable adherence to, or implementation of, a recommendation.

L_4 Drugs are not publicly funded. Costs are assumed by the patients (self pay), third party insurers, and/or pharmaceutical company compassionate use programs. This category includes treatments at cancer centres/hospitals (category A) and private infusion clinics (category B).

CACC prefers to use the generic drug name but reverts to the brand name for convenience and understandability in several instances. For example, trastuzumab is Herceptin, yttrium-90 ibritumomab is Zevalin and bortezomide is Velcade.

Explanation of Tables

The following explains how some of the various designations in table 1 are to be interpreted in each province for each drug.

The ✔ designation standing alone indicates full public funding was available for anyone with that specific disease indication in 2006. The application process for the drug was a simple prescription procedure by the attending oncologist

The combined ✔ L_1 designation indicates a provincial policy that full public funding will be available for anyone with that specific indication, but only through a more detailed case-by-case application by the attending oncologist. Disease-specific criteria apply and these may vary by province. This would ensure selected patients were receiving the drug and would enable future tracking and analyses of treatment outcomes (phase 4 trials or post-marketing evaluations). The case-by-case application procedure by itself might constitute a barrier to access if it were very complex, time-consuming to initiate and slow to respond, but this was not studied.

The L_1 designation without an accompanying ✔ indicates full public funding was not available but that an exceptional access application process was in place. This required a detailed case-by-case application process by the attending oncologist to make the drug available to some subsets of patients with specific indications. Application might not necessarily result in approval and payment could be all private or a combination of public and private.

In the absence of a stand-alone ✔ designation, the L_1, L_2, L_3 and L_4 designations defined in the Methodology section can be simultaneously operative within a province.

An increasing proportion of the studied drugs are funded by self pay or third parties and administered within publicly funded cancer centres.

Example 1

In BC, Tarceva for salvage treatment of non-small cell lung cancer is fully funded for all patients but requires utilizing the BC Cancer Agency Compassionate Access Program which is a case-by-case, special access program (✔ L_1 designation).

In Alberta, Tarceva was fully funded in 2006 as an Alberta Cancer Board Group 2 drug and available for all patients through designated prescribers (✔designation).

In Ontario, Tarceva was approved in 2006 for "limited use" for the same indication through the Drug Benefit (ODB) program, which covers only seniors and social assistance cases (L_2 designation indicating only limited patient groups were covered). Others must resort to private pay options (L_4 designation). Hence Tarceva has combined L_2 L_4 descriptors in Ontario.

Less than ten per cent of Saskatchewan patients with metastatic colorectal cancer have opted to pay for Avastin when offered the choice.

Example 2

In BC, adjuvant oxaliplatin for high risk colon cancer is fully funded for all patients with that condition but because it is not yet been approved in Canada (i.e., has not received a Notice of Compliance), it must be applied for on a case-by-case basis (also true across the country); hence ✔ L_1 designation.

In Alberta, full public funding has not yet been provided (X), although a recommendation has been written

TABLE 1 **CANCER DRUG ACCESS AND FUNDING BY DRUG AND PROVINCE** (STATUS AS OF DEC. 31, 2006)

DRUG AND INDICATION	ACCESS	BC	AB	SK	MB	ON	QC	NB	PEI	NS	NL
capecitabine (Xeloda) Adjuvant treatment of Duke C colon cancer	P S	✔	✔	✔	✔	L2 L4	✔ L1	C L2 L4	X	C L1 L2 L4	C L1 L2 L4
oxaliplatin (Eloxatin) FOLFOX adjuvant treatment of colon cancer	P	✔ L1	X R L1 L4	✔ L1	✔ L1	R L1 L3 L4	✔ L1	✔ L1	X L1	X L1 L3 L4	✔ L1
oxaliplatin (Eloxatin) Metastatic colorectal cancer	P	✔ L1	X R L1 L4	✔ L1	✔ L1	R L1 L3 L4	✔ L1	✔ L1	✔ L1	X L1 L3	✔ L1
pemetrexed (Alimta) With Cisplatin for mesothelioma	P W	✔	✔	✔ L1	✔ L1	X L3 L4	X L1 L3	✔ L1	R	X	✔
temozolomide (Temodal) With XRT and 6 months maintenance for GBM	PS	✔	✔	✔	✔	L1 L2 L4	✔	C L2 L4	X	C L1 L2 L4	✔ L4
trastuzumab (Herceptin) Adjuvant treatment of her2/neu positive breast cancer	P	✔	✔	✔	✔	✔	✔	✔	L1	✔	✔
rituximab (Rituxan) CHOP-Rituxan for DLC, B-cell non-Hodgkin's lymphoma	P	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
bevacizumab (Avastin) With chemotherapy for metastatic colorectal cancer	P	✔ L1	X L4	X L4	X	X R L4	X L3 L4	X L3	X	X L3 L4	✔
cetuximab(Erbitux) With chemotherapy for metastatic colorectal cancer		X	X	X	X	X	X	X L3 L4	X	X	X
alemtuzumab (Campath) Relapsed chronic lymphocytic leukemia		✔ L1	X L4	✔ L1	X L1	X L4	✔ L3	X L1 L3	X	L1	X
I-131 tositumomab (Bexxar) Relapsed NHL		✔ L3	X	X	X	X	X L1 L3	X	X	X	X
yttrium-90 ibritumomab (Zevalin) Relapsed NHL		✔ L3	L4	X	✔ L1	X L4	X L1 L3	L1 L3	X	X	L1 L3
AI – anastrazole (Arimidex) Adjuvant treatment of ER positive breast cancer	CS	✔	✔	X R L4	✔	L2 L4	✔	C L2 L4	X C	L2 L4	C L1 L2
AI – letrozole (Femara) Adjuvant treatment of ER positive breast cancer	CS	✔	✔	X R L4	✔	L2 L4	✔	C L2 L4	X C	L2 L4	C L1 L2

Continued on facing page

This table is the simplified version of what oncologists and patients face on the day a treatment choice has to be made. An array of additional terms and conditions underlie these broad categories. Added to all these variables is the human one: the ability or willingness of oncologists and patients to deal with this confusion.

DRUG AND INDICATION	ACCESS	BC	AB	SK	MB	ON	QC	NB	PEI	NS	NL
AI – exemestane (Aromasin) Adjuvant treatment of ER positive breast cancer	CS	✔	✔	X R L4	✔	L1 L2 L4	✔	C L2 L4	X C	X	C L1 L2
bisphophonate – clodronate (Various/generic) Reduce bone complications from metastatic breast cancer	S	✔	✔	✔	✔	L2	✔	C L2 L4	X L4	L2 L4	X
bisphophonates – pamidronate (Various/generic) Reduce bone complications from metastatic breast cancer		✔	X L4	✔	✔	✔	✔	✔	✔	✔	✔
bisphophonate – zoledronate (Zometa) Reduce bone complications from metastatic breast cancer	P	X	X	X	X	X	✔ L1 L3	X	X	L1 L3	X L1
thalidomide (Thalomid) Relapsed multiple myeloma	C	X C L2 L4	X C L4	X C	X C L4	X C	C L1 L3	X C	X C	X C	C L1 L2
bortezomib (Velcade) Relapsed multiple myeloma		✔ L1	✔	✔	✔	✔	✔	✔ L1	X	✔	✔ L1
erlotinib (Tarceva) Non-small cell lung cancer	PC S	✔ L1	✔	X	✔	L2 L4	✔	C L2 L4	X	X C L1 L2	X C L2 L4
gefitinib (Iressa) Non-small cell lung cancer		X	X	X	X	X	X	X	X	X	X
imitanib(Gleevec) Chronic myelogenous leukemia	PC S	✔	✔	✔	✔	L2 L4	✔ L1	C L2 L4	✔	C L1 L2	✔
imatinib(Gleevec) Gastrointestinal stromal tumour	PC S	✔	✔	✔	✔	L1 L2 L4	✔ L1	C L2 L4	✔	C L1 L2	C L1 L2

✔ Approved and fully funded in that province
X Not approved or funded in that province
L1 Limited access on a case to case basis (disease specific factors)
L2 Limited access based on coverage for only specific patient groups (patients factors such as over 65, or receiving social assistance or welfare cases)
L3 Limited access based on variable access in that province (institutional factors; only available in some centres but not others)
L4 Limited access based on private payment of the drug (self-pay, third party insurer or manufacturer's compassionate program) but administration of the drug provided by public cancer centre or hospital
R Recommended for funding but not yet funded; approval still in process for decision
S Self pay or third-party insurer, drug readily available through retail pharmacies
P Pharmaceutical company sponsored reimbursement /assistance program
C Compassionate release from pharmaceutical company
W Funded through WCB (Workers' Compensation Board) or WSIB (Workplace Safety and Insurance Board) in Ont.
D Funded partly by donated monies from charitable source or foundation
T Available by multi-centre Canadian clinical trial currently open or soon to open as of December 2006

Shaded areas depict changes since 2005

The western provinces, with their more integrated oncology drug budgets that include both parenteral and oral/take-home drugs, have better and more uniform access to cancer drugs than provinces with multiple funding plans.

by the physician expert groups (R). Case-by-case application has to be made for the same reason as in BC (hence L_1) and at present it is funded predominantly by the pharmaceutical manufacturer's assistance program (L_4). Hence, the X R L_1 L_4 descriptor.

In Ontario, guidelines have been written for use of adjuvant oxaliplatin (R) and it is provided to patients on a case-by-case basis (L_1). However, some centres may cover the cost of the drug and its administration while others do not (L_3 designation indicating variable institutional practices for funding patients). In some centres patients pay (L_4 designation) for the full cost of the drug or the residual not covered by the hospital global budget. Other centres charge for the drug but cover residual costs through hospital global budgets (L_4). Hence, the R L_1 L_3 L_4 descriptor.

Results

The full tabulation of access and funding for the 24 cancer drugs is shown in Table 1. Shaded areas indicate the substantive changes in access from last year. The table presents a very complex picture. To enable the reader to better understand the data, subsets are presented in Tables 2, 3 and 4. However, rather than relegate Table 1 to an appendix, it appears here in order to emphasize visually the extreme variability of cancer drug funding in Canada and to enable interested parties to assess the issues more completely. British Columbia still leads the nation with the most comprehensive access to cancer drugs.

Table 2 summarizes the number of drugs funded in each province. Drugs that had no costs incurred by patients and were regularly made available to the appropriate group were classified as ✔L_1 and are included under column 2 (approved and funded).

Products recommended by clinicians but still in the review process for funding (recommended but not funded) are shown in column 4. Drugs newly funded in 2006 are shown in column 6. Drugs not approved/funded by provinces that allow private pay options within public facilities were identified in column 7. The number and names of specific drugs for which funding was withdrawn in 2006 are shown in column 8.

As shown in Table 2 the four western provinces have approved and funded more drugs than provinces east of the Manitoba border, except for Quebec. However, the number of drugs accessed in Quebec must be regarded with some circumspection, given the variability from hospital to hospital in that province.

For some specialized drugs or treatments, such as Bexxar and Zevalin, it may be appropriate to limit availability to specialized centres with sufficient expertise (in this case, handling radioactive drugs) and volume to administer the treatment safely.

Table 3 displays the impact on access to cancer drugs arising from four broad categories of limited access. Ontario has more restrictions than any other province (column 3) while the four western provinces have the fewest (column 4). PEI also has few restrictions in this grouping, because more drugs are not funded at all. Of special interest is the use of L_4 – private pay – across the provinces. As noted in last year's Report Card, the eastern provinces rely more heavily than other provinces on compassionate programs offered by manufacturers. Although the same programs exist at least to some extent in the rest of the country, the extensive use of the private pay option in Ontario (14 of the 24 studied drugs) indicates a larger contribution by insurers and individual patients.

Table 4 summarizes the status of private pay options for each drug within each province. Though it is an oral drug, thalidomide is included within the parenteral list because it does not have Health Canada approval and is not available through retail pharmacies. In the last CACC Report Card, the only province with significant self pay options for parenteral drugs was Alberta. This Report Card documents an increasing proportion of the studied drugs being funded by self pay or third parties and administered within publicly funded cancer centres (category A) or private infusion clinics (category B).

Provis has been operating one such private clinic in Toronto since 2005 and Bayshore is opening more than

20 clinics across the country. Bayshore Infusion Clinics are a collaborative enterprise involving Roche Pharmaceuticals Canada Inc. (which is licensed for Avastin, Herceptin, Rituxan, Xeloda, and Tarceva), Bayshore Clinics (which provides the facilities), and McKesson Canada (which administers the drug reimbursement support).

CANCER DRUG ACCESS BY PROVINCE

BRITISH COLUMBIA (BC)

In 2006, BC funded 20 of the 24 studied drugs and continues to fund more than any other province.

Avastin continues to be provided on a case-by-case basis for first-line palliative treatment of metastatic colorectal cancer when used with combination chemotherapy. However, as formal funding from the Ministry of Health is still awaited, the cost of the Avastin program has strained the BC provincial oncology drug budget and limited the introduction of other new cancer treatments also funded through this mechanism.

Two drugs were withdrawn from funding in 2006: thalidomide for relapsed multiple myeloma and Iressa for advanced non-small cell lung cancer. Both represent unique situations.

Thalidomide had undergone an 11-fold increase in cost from its manufacturer over the several years it was funded in BC. While existing patients who benefit from thalidomide continue to receive the drug free, new patients must apply to the manufacturer's compassionate release or assistance program, or acquire the drug through self pay or third parties. This is the first time within the BC Cancer Agency (BCCA) regional centres that a drug will be acquired by the BCCA and charged to the patient. Unlike other oral drugs, thalidomide cannot be provided to retail pharmacies because it does not have NOC (notice of compliance) from Health Canada and is available only through a Special Access Program administered by BCCA.

Conditional approval for Iressa was withdrawn by Health Canada because of a lack of survival benefit from longer-term results of important clinical trials

Three private Bayshore Infusion clinics are slated to open in BC.

ALBERTA (AB)

In 2006, Alberta fully funded an additional six of the 24 drugs studied. Of particular note, adjuvant Herceptin, which had been temporarily funded by the Alberta Cancer Foundation's donated/charitable monies, was finally funded by the provincial government.

The aromatase inhibitors, Arimidex, Aromasin and Femara, used in treating hormone receptor positive breast cancer, underwent protracted evaluation for drug interchangeability and possible designation of one of them as "preferred". This approach was abandoned and all three were finally approved for the separate adjuvant indications initially listed.

One drug was de-listed from funding by the Alberta Cancer Board: thalidomide (similar to BC). Access is now through Celgene's compassionate access program, as is utilized in other provinces, or through self pay or third party coverage.

Alberta has a long tradition of allowing third party insurers or self pay for cancer drugs within the Alberta Cancer Board (ACB) centres, usually under a designation known as "Director's Privileges" (category A). Of the 12 drugs not publicly funded by the ACB in 2006, six were delivered to patients through this mechanism and/or through pharmaceutical company assistance programs as shown in Table 4. Administrative costs such as for nursing and pharmacy are then borne by the ACB.

At this time, there are no plans for a Bayshore Infusion Clinic in Alberta, possibly because of this self pay option within ACB.

SASKATCHEWAN (SK)

In 2006, Saskatchewan provided funding for two additional studied drugs: oxaliplatin in the adjuvant setting for high-risk Dukes C colon cancer (it was provided previously only on a case-by-case basis) and Velcade for third-line treatment of myeloma.

Drug funding of Avastin for metastatic colorectal cancer was not approved by the Ministry of Health. As a result, the Saskatchewan Cancer Agency (SCA) developed a Self Pay Drug Program (SPDP) making it available but paid for by patients. The costs of drug delivery and administration are absorbed within the existing SCA budget. The SPDP limits the spectrum of drugs covered and so far, only two have been included: Avastin and maintenance Rituxan for follicular non-Hodgkin's lymphoma. Only a small percentage of patients with metastatic colorectal cancer (estimated at less than ten per cent), when offered Avastin as one of their informed options for treatment, have opted to pay for it. SCA has formal guidelines and letters to patients describing the SPDP option.

In researching this Report Card, CACC discovered an error in classifying the three aromatase inhibitors as being partly funded in 2005. In fact they were not publicly funded. Hence, support for cancer drugs in Saskatchewan was less than reported last year.

At this time there are no plans for a Bayshore Infusion Clinic in Saskatchewan.

MANITOBA (MB)

In 2006, Manitoba added four studied drugs for funding. In addition, a process was developed for funding

TABLE 2 **SUMMARY OF CANCER DRUGS ACCESS AND PUBLIC FUNDING**
(STATUS AS OF DEC. 31, 2006)

PROV.	APPROVED AND FUNDED	LIMITED ACCESS/ FUNDING	RECOMMENDED BUT APPROVAL CYCLE NOT COMPLETED & NOT PUBLICLY FUNDED	NOT APPROVED OR FUNDED	INCREMENTAL DRUGS FUNDED IN 2006 FROM PREVIOUS YEAR	NOT APPROVED BUT SELF PAY OR 3rd PARTY OPTIONS WITHIN PROVINCIAL CENTRES	DRUGS FUNDING WITHDRAWN IN 2006
BC	20 (14+6)	1 thalidomide	0	3	0	1 thalidomide	-2 thalidomide Iressa
AB	13 (13+0)	5 Avastin, Campath, Zevalin, Pamidronate, thalidomide	2 oxaliplatin (adjuvant); oxaliplatin (metastatic)	4	+6 Herceptin, Arimidex, Femara, Aromasin, Velcade, Tarceva	6 oxaliplatin (adjuvant), oxaliplatin (metastatic), Avastin, Zevalin, pamidronate, thalidomide	-1 thalidomide
SK	13 (9+4)	1 Avastin	0	10	+2 Velcade, oxali-platin (adjuvant)	1 Avastin	0
MB	17 (13+4)	2 Campath, thalidomide	0	5	+4 oxaliplatin (adjuvant),Velcade, Tarceva, Zevalin	0	-1 Avastin
ON	4 (4+0)	10 Xeloda, Alimta, Temodal, Arimidex, Femara, Aromasin, clodronate, Tarceva, Gleevec (CML), Gleevec (GIST)	3 oxaliplatin (adju-vant), oxaliplatin (metastatic), Avastin	7	+4 Xeloda, Velcade, Tarceva and Gleevec for CML	3 Avastin#, oxaliplatin (adjuvant)#, oxaliplatin (metastatic)#	-1 Iressa
QC	15* (12+3)	7 Alimta, Avastin, Campath, Bexxar, Zevalin, thalidomide, Zometa	0	2	+1 Velcade	0	0
NB	7 (3+4)	13 Xeloda, Temodal, Avastin, Campath, Erbitux, Zevalin, Arimidex, Femara, Aromasin, clodronate, Tarceva, Gleevec (CML), Gleevec (GIST)	0	4	+2 Zevalin, Tarceva	1 Avastin	-1 Avastin
PEI	5 (4+1)	3 oxaliplatin (adjuvant), Herceptin, Campath	1 Alimta	15	+2 Gleevec for CML, Gleevec for GIST	0	0
NS	4 (4+0)	13 Xeloda, oxaliplatin (adjuvant), oxaliplatin (metastatic), Temodal, Avastin, Campath, Arimidex, Femara, clodronate, Zometa, Tarceva, Gleevec (CML), Gleevec (GIST)	0	7	+3 Xeloda,Herceptin, Velcade	1 Avastin	0
NL	10 (7+3)	9 Xeloda, Zevalin, Arimidex, Femara, Aromasin, Zometa, thalidomide, Tarceva, Gleevec (GIST)	0	5	+3 Xeloda, Avastin, Zevalin	0	0

* See notes to Quebec "approval". Approval does not automatically translate into access.

\# Minority or proportion of centres only

and providing Zevalin (a radio-labeled antibody for relapsed non-Hodgkin's lymphoma). A similar radioimmunotherapy treatment, Bexxar, is not currently available although a clinical trial of Bexxar did complete accrual in 2006 in Manitoba and other sites across the country.

Avastin was turned down for funding for metastatic colorectal cancer and no self pay option is available within CancerCare Manitoba.

A private Bayshore Infusion Clinic is due to open in Winnipeg to provide alternatives for patients requiring unfunded cancer treatments.

All provinces improved access to the studied drugs to some degree, or, in the case of BC, maintained good access. However, this has come with limits, conditions and barriers.

ONTARIO (ON)

In 2006, Ontario provided funding for four additional studied drugs; three of these are oral drugs only offered to selected populations. However, there is still considerable variation in how a number of other important drugs are provided. Adjuvant oxaliplatin (as part of the FOLFOX regimen) for Dukes C colon cancer and palliative oxaliplatin for metastatic colorectal cancer are now routinely provided to patients in Ontario at all of the 14 Cancer Care Ontario (CCO) regional cancer centres, but with varying payment arrangements. A Sanofi-Aventis sponsored patient assistance program covers a significant portion of the drug cost for many patients. Some centres cover the rest of the cost (10-20 per cent) but other centres require patients to pay the residual. When Sanofi-Aventis receives an NOC for oxaliplatin, expected in 2007, the company's assistance program will likely cease. It is uncertain what steps Ontario will take to make this drug available to patients at that time.

In 2006, the Ontario government tabled and passed Bill 102, the Transparent Drug System for Patients Act, which was to initiate sweeping changes in the way drugs are reviewed, approved and funded[2]. It was designed to make broad systemic changes to contain the burgeoning Ontario Drug Benefit (ODB) budget, which exceeded $2.7 billion dollars in 2006. The Act's impact on cancer drug access remains to be seen, especially with respect to exceptional access for hospital-based cancer treatments. The goals were to improve patient access to drugs through new conditional listings, exceptional access and rapid reviews of breakthrough drugs, to name only a few of the commitments. One of the seven rapid reviews now underway is for an oncology product, and four cancer drugs were added to the approved lists. Other elements of this comprehensive package are moving forward, albeit slowly, without significant impact on cancer drug access. The same restrictive processes remain in place for access to many cancer drugs.

A process for exceptional access to hospital-based cancer drugs does not exist in Ontario.

Also in 2006, CCO submitted a proposal[3] to the Ministry of Health and Long Term Care (MOHLTC) describing a mechanism for providing unfunded cancer drugs within the 14 publicly funded CCO regional cancer centres. Under this proposal, patients would pay for the drugs themselves or through third party insurance and the regional cancer centre would administer the drugs. An administrative fee of $250 ($2,500 for radioactive drugs) per infusion would be charged to the patient for recovery of nursing and pharmacy costs. The ministry has not yet responded or commented publicly on the CCO proposal. Some regional cancer centres have already implemented this self pay or third party coverage in 2006 and others are expected to begin early in 2007, dropping the administrative fees and instead marking up the cost of the drug.

Nine new Bayshore Infusion Clinics are open or soon to open in Ontario.

QUEBEC (QC)

Two advisory bodies have recently emerged in Quebec to provide recommendations on drugs: the Comité d'évolution des pratiques en oncology (CEPO) and the PGTM, a professional body of the four academic pharmacies (University of Quebec, University of Sherbrooke, McGill University and the University of Montreal). These bodies have professional but not fiscal jurisdiction. Funding decisions on drugs are ultimately placed in the hands of individual hospitals. Consequently,

variations exist in drug access from hospital to hospital. Hence, the Quebec data remain incomplete. Our resources do not allow us to survey every hospital to more accurately scope variability for each drug. The situation deserves a more detailed study with methodology geared specifically for Quebec.

In 2006, one additional cancer drug was widely funded in Quebec: Velcade.

Avastin for treatment of metastatic colorectal cancer was declined for addition to the Conseil de Medicament provincial drug formulary, despite a provincial CEPO guideline. A small number of centres were providing Avastin for this indication through alternate payer options. CACC was unable to document the extent of this practice.

Six private Bayshore Infusion Clinics have opened or are soon to open in Quebec.

"The definition of what is too expensive is in the eye of the beholder (i.e.,stakeholder)." [4]

NEW BRUNSWICK (NB)

In 2006, New Brunswick funded another two of the studied drugs: Zevalin and Tarceva.

Avastin was declined for funding, although several patients had received treatment to that point. However, Avastin and Erbitux have been made available through private pay options within public hospitals.

The four hospital-based cancer clinics in New Brunswick have a physician-driven process for accessing cancer drugs, that results in modest access for hospital-based cancer drugs. A provincial cancer program is in development, but a cancer drug committee is not yet established. New Brunswick lacks a provincial oncology drug budget and a cancer drug formulary.

A Bayshore Infusion Clinic is slated to open in New Brunswick for private infusion chemotherapy.

PRINCE EDWARD ISLAND (PEI)

In 2006, PEI began to fund two indications for the studied drug Gleevec: chronic myelogenous leukemia (CML) and gastro-intestinal stromal tumours (GIST).

In researching this Report Card, CACC discovered an error in classifying the three aromatase inhibitors as being partly funded in 2005. In fact they were not publicly funded. Hence, support for cancer drugs in PEI was less than reported last year.

No private infusion clinics are slated to open in PEI as of the writing of this report.

NOVA SCOTIA (NS)

In 2006, Nova Scotia fully funded an additional three of the studied drugs: Xeloda, Velcade and Herceptin. A process was introduced for evaluating new cancer drugs,that utilizes scientific evidence, a pharmacoeconomic analysis and an ethical framework. Avastin and Velcade were the first drugs evaluated through this new process. Velcade was funded but Avastin was not. Cancer Care Nova Scotia (CCNS) continues to work toward a provincial oncology drug budget for parenteral drugs. Oral cancer drugs for the most part continue to be provided under the provincial Pharmacare plan, which covers only seniors and patients receiving social assistance.

In 2006 the Nova Scotia government introduced legislation allowing private clinics. These are required to be licensed and to undergo audits and inspections. Such clinics can offer insured services if there is a contract with the provincial government, as well as uninsured services (diagnostic services and minor surgical procedures). One of the two provincial cancer clinics allows private pay.

Two private Bayshore Infusion Clinics are opening in Nova Scotia.

NEWFOUNDLAND AND LABRADOR (NL)

In 2006, NL implemented full funding for Avastin and became the payer of last resort for Xeloda. Oral aromatase inhibitors for adjuvant breast cancer are still not funded but continue to be provided through compassionate access from pharmaceutical companies.

No private pay options have been needed as most

TABLE 3 **SUMMARY OF LIMITED ACCESS VARIABLES FOR CANCER DRUGS**

(Status as of Dec. 31, 2006)

	L1 Case by case review	L2 Specific groups only	L3 Variable across the prov.	L4 Private pay	# limitations to access the 24 drugs studied
BC	6	1	2	1	10
AB	2			6	8
SK	4			4	8
MB	5			1	6
ON	5	9	3	14	31
QC	10		7	1	18
NB	6	9	4	10	29
PEI	3			1	4
NS	9	8	4	7	28
NL	11	7	1	3	22

parenteral cancer drugs have been funded through the provincial oncology drug budget.

The provincial drug plan, previously limited to seniors and people receiving social assistance, will expand January 31, 2007 to include low-income families and wage earners not previously covered. With this expansion, 40 per cent of the population will be covered.

To our knowledge, no private infusion clinics for cancer drugs have opened or are currently planned for Newfoundland and Labrador.

Discussion

The methodology used in this study, as in the 2005 Report Card[1], is patient-focused. When assessing access to the drugs, CACC sought to determine whether and under what circumstances drugs were made available to cancer patients, with particular interest in the costs incurred by patients. This pan-Canadian review differs from how individual provincial cancer agencies may account for or publicly describe their cancer drug funding, or analyze issues and practices pertinent to their province.

Despite hearsay accusations that the Report Card methodology lacks accuracy, none of the provincial cancer organizations, health ministries, Health Canada, or any other cancer organization has formally challenged any of the Report Card findings on access to drugs.

In fact, the only significant errata from last year's report of which we are aware relates to the overestimate of PEI and Saskatchewan funding for aromatase inhibitors. We thought they were funded and they were not. Other errata in other provinces had to do with minor details not leading to any substantive difference in the final availability or classification for patients, or overall conclusions.

Table 1 shows detailed funding patterns for each drug in each province. It should be emphasized that the situation is continually in a state of flux. It varies by institution, the point in the approval and funding process in each province/hospital, and as incoming information alters clinical practice. The situation requires constant monitoring so that as significant changes in patterns emerge, corresponding changes in government policies and clinical practice can be introduced. This must occur in timely fashion.

Reporting on the ability of patients to access cancer drugs is complicated and confounded by jurisdictional differences in methodology and terminology. To overcome that problem CACC established a working classification to describe the degrees of limited access. This enabled us to identify more precisely the various barriers to access in each province and formulate better interprovincial comparisons.

TABLE 4 **PARENTERAL CANCER DRUGS PROVIDED BY PRIVATE PAY OPTIONS, BY PROVINCE**
(STATUS AS OF DEC. 31, 2006)

DRUG AND INDICATION	ACCESS	BC	AB	SK	MB	ON	QC	NB	PEI	NS	NL
oxaliplatin (Eloxatin) FOLFOX adjuvant treatment of colon cancer	P		A			A					
oxaliplatin (Eloxatin) Metastatic colorectal cancer	P		A			A					
pemetrexed (Alimta) With Cisplatin for mesothelioma	PW										
trastuzumab (Herceptin) Adjuvant treatment of her2/neu positive breast cancer	P										
rituximab(Rituxan) CHOP-Rituxan for DLC, B-cell non-Hodgkin's lymphoma	P										
bevacizumab (Avastin) With chemotherapy for metastatic colorectal cancer	P		A	A		A B	A	A		A	
cetuximab(Erbitux) With chemotherapy for metastatic colorectal cancer						B					
alemtuzumab (Campath) Relapsed chronic lymphocytic leukemia			A								
I-131 tositumomab (Bexxar) Relapsed NHL											
yttrium-90 ibritumomab (Zevalin) Relapsed NHL			A			B					
bisphophonates – pamidronate (Various/generic) Reduce bone complications from metastatic breast cancer			A								
bisphophonate – zoledronate (Zometa) Reduce bone complications from metastatic breast cancer	P										
thalidomide (Thalomid) Relapsed multiple myeloma	C	A	A								
bortezomib (Velcade) Relapsed multiple myeloma											

A Private pay or third party funded option within provincial cancer agency centre or clinic
B Private infusion clinic for cancer (i.e. Bayshore Infusion Clinics or Provis Infusion Clinic)
P Pharmaceutical company sponsored reimbursement /assistance program
C Compassionate release from pharmaceutical company
W Funded through WCB (Workers' Compensation Board) or WSIB (Workplace Safety and Insurance

TRENDS IN CANCER DRUG ACCESS IN CANADA

1) Improved funding and availability of the studied cancer drugs

All provinces improved access to the studied drugs to some degree or, in the case of BC, maintained good access. Alberta funded the most new drugs (six). Ontario lags behind many provinces in funding cancer drugs and has the most variability in access, particularly by sub-region. Given that Quebec "approval" does not necessarily mean access, the variability is at a more local (hospital) level and more difficult to document. Table 2 shows that the four western provinces approve and fund more cancer drugs than do the other provinces. This disparity in cancer drug access coincides with the west-east provincial gradient in cancer mortality documented in previous Report Cards.

In the case of the three aromatase inhibitors for adjuvant breast cancer, Alberta eventually funded all three and abandoned the idea of funding only one as the preferred agent. The interchangeability of aromatase inhibitors remains to be proven. There are theoretical and clinical reasons why these products may not turn out to be interchangeable for all patients.

When particular attention was paid to "limited access" CACC found that improvements in access to studied drugs have come with limits, conditions and barriers. The collage is symptomatic of the patchwork design of drug plans, leading to hurdles between the prescription and the treatment. For patients, the limitations materialize as systematic barriers to treatment.

Most provinces appear to have a preference for the type of limited access that will be deployed. BC, Manitoba, Quebec and Newfoundland lean toward case-by-case review; Ontario and New Brunswick use the private-pay option more often than other provinces; Ontario, New Brunswick, Nova Scotia and Newfoundland target their drug plans toward seniors and social assistance, although Newfoundland has just announced an expansion of its program to lower-income families.

It must be noted that for some patients it is irrelevant whether payment comes from the government, insurers or compassionate programs of manufacturers. Access is access. The distress comes from having to locate the appropriate payer while battling the disease and the fear of not finding one.

It would appear that provinces with more integrated, oncology drug budgets that include both parenteral and oral/take home drugs (i.e. the western provinces) have better and more uniform access to cancer drugs than those with multiple funding plans.

2) Emergence of self pay options within the public system and private clinics

Last year in Canada, only Alberta had a formal self pay program for cancer therapeutics within the provincial cancer agency. Now, the private pay option within the public system is increasing in five additional provinces (Saskatchewan, Ontario, New Brunswick, Nova Scotia and British Columbia).

As well, private infusion clinics emerged and expanded in 2006. As described in the results section, at least 20 Bayshore Infusion Clinics have opened or will have opened by the end of 2007 in six provinces.These private clinics will challenge provincial cancer centres and hospitals to continue to provide potentially important new treatments, both curative and palliative, within the public system.

How many new cancer drugs will be added in the future to the self-pay option is uncertain. Cancer patients facing self pay, especially those without insurance coverage, fear their governments will increasingly offload the expense regardless of whether patients can afford to pay. Patients also complain that cancer is unreasonably targeted for self pay while people dealing with other life-threatening diseases are not expected to pay for the cost of their hospital care.

For most Canadians, self pay for most of the studied drugs would mean financial disaster. For others, a third party insurance plan purchased in better times might prove inadequate, especially if annual caps or other constraints make only a dent in the total cost.

At this time, most of the drugs studied are indicated for palliation (15 of 24) but in time, many could be found to be curative or to exert profound benefit in other contexts. Evaluating and funding the new applications for this new class of cancer treatment drugs presents a major challenge for the organized cancer system.

3) Increased concordance between provinces in funding for certain drugs for specific indications

There appears to be increasing concordance between provinces in funding for a number of drugs, among them Rituxan with CHOP chemotherapy for aggressive non-Hodgkin's lymphoma, oxaliplatin for both metastatic and adjuvant indications, bisphosphonates

for metastatic breast cancer to bone, Herceptin for adjuvant breast cancer, Xeloda for adjuvant colon cancer, Temodal for glioblastoma multiforme, Velcade for myeloma, and Gleevec for CML, and GIST.

During 2006 there was increasing agreement between provinces on which cancer drugs not to fund: Erbitux for metastatic colorectal cancer, Iressa for lung cancer, Zometa for metastatic breast cancer to bone, thalidomide for myeloma, and possibly Avastin for colorectal cancer. This degree of concordance might indicate hope for development of national guidelines for cancer care and consistent, reliable availability of new treatments across the country.

4) Continued lack of explicit cost-effectiveness analysis and transparency of decision-making

There is very little disclosure or transparency in the decision making for funding of expensive drug treatments. Pharmaceutical companies and ministries of health have generally not shared their cost effectiveness models or the threshold at which treatments are funded or rejected.

It is clear that cost is the main decisive factor in rejecting expensive new treatments, even when evidence of effectiveness is strong. The interesting experience of Saskatchewan in terms of Avastin (provided through the Saskatchewan Cancer Agency Self Pay Drug Program) and Alberta's long-standing self pay model suggests that when patients understand the reasoning behind palliative as opposed to curative treatment, they may accept provincial funding restrictions and alternate coverage models. In order to achieve this, however, what is needed is an explicit process and transparency of how such decisions are made.

Without transparency there will always be public uncertainty, media pressure and scrutiny, and frustration on the part of health providers.

5) Increased movement towards a National Pharmaceuticals Strategy

Another critical initiative has been the Federal/Provincial/Territorial work to develop a National Pharmaceuticals Strategy. A list of priorities that includes a catastrophic drug plan was tabled in June 2006. It remains to be seen how inclusive such a plan would be for new cancer drugs.

On November 23, 2006, the federal government allocated $260 million over five years to implement a nationwide cancer control strategy by the newly-created Canadian Partnership Against Cancer (CPAC)[5]. CPAC should make interprovincial collaboration on timely patient access to effective cancer drugs an agenda priority.

Conclusions and Recommendations

While 2006 brought some improvements in cancer drug access, there remains much to be done. CACC believes that cancer patients should have the right to access the medications and services that will save, extend or improve their lives, wherever they live in Canada. How decisions are made regarding access to new cancer therapies should be more transparently linked to the many necessary funding partners – governments, pharmaceutical companies, third party payers, self payers and institutional sources. Given the mounting cost of cancer drugs, all groups must increasingly collaborate to find solutions.

Recommendations

1 Establishment of a national catastrophic drug strategy and drug plan;
2 Development and implementation of Canada-wide guidelines in a timely and consistent manner to speed access and provide national consistency;
3 Introduction of an ongoing evaluation process for new drugs which includes a robust pharmacoeconomic model;
4 Establishment of a single oncology drug budget and formulary in each province integrating parenteral and take-home cancer drugs;
5 Increased translational research to identify the subsets of patients who benefit from the new drugs (see "Research Saves Lives" in this Report Card);
6 Insistence upon phase 4 (post-approval) trials to confirm treatment results in the cancer population at large;
7 Incorporation of substantial patient involvement into decision-making;
8 Transparency about decision-making;
9 A repository of accurate information regarding applicable funding sources for each drug whether government ministries, third party insurers, research agencies, or compassionate assistance programs of pharmaceutical companies.

References

1. Cancer Drug Access in Canada. CACC Report Card 2005, 9: 26-38. (www.canceradvocacy.ca/)
2. Bill 102, Transparent Drug System for Patients Act. Government of Ontario, 2006. (http://www.health.gov.on.ca/english/public/legislation/drugs/hu_drugsact.html)
3. Report of the Provincial Working Group on the Delivery of Oncology Medications for Private Payment in Ontario Hospitals (submitted to Ontario Ministry of Health and Long Term Care July 27, 2006. (http://www.cancercare.on.ca/documents/Report_on_Unfunded_Cancer_Drugs.pdf)
4. Meropol NJ, Shulman KA: Perspective on the cost of cancer care, *Journal of Clinical Oncology*, 2007; vol 25, p.184
5. Canadian Partnership Against Cancer. Prime Minister's announcement November 23, 2006. (http://www.pm.gc.ca/eng/media)