



# Systemic Therapy Update

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*Available on website [www.bccancer.bc.ca](http://www.bccancer.bc.ca)*

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## HIGHLIGHTS OF PROTOCOL CHANGES

Several sarcoma (OSVIM, SAIME, SAVIM) protocols have been revised based on the 2002 ASCO guidelines on chemotherapy protectants. This includes the use of lower dose mesna regimens and the option of using the oral administration of mesna for appropriate patients receiving high dose ifosfamide.

Similar changes to ifosfamide-based genitourinary protocols (GUVIP2, GUVIEP) will be made next month.

## BENEFIT DRUG LIST

The current Benefit Drug List, Class II forms and Undesignated Indication Application forms are available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms.

## LIST OF NEW AND REVISED PROTOCOLS

**INDEX to BC Cancer Agency Protocol Summaries** revised monthly (includes tumour group, protocol code, indication, drugs, last revision date and version). Protocol codes for treatments requiring “Undesignated Indication” approval prior to use are prefixed with the letter U.

- **LYHDMTXP** revised (methotrexate level clarified): Treatment of primary intracerebral lymphoma with high dose methotrexate
- **LYHDMTXR** revised (methotrexate level clarified): Treatment of leptomeningeal lymphoma or recurrent intracerebral lymphoma with high dose methotrexate
- **OSVIM** deleted (replaced by SAIME): Therapy for advanced sarcomas using etoposide (VP-16), ifosfamide-mesna
- **SAIME** new (replacing SAVIM and OSVIM): Etoposide, ifosfamide-mesna for patients with newly diagnosed Ewing's sarcoma/peripheral neuroectodermal tumor (PNET) or rhabdomyosarcoma or advanced soft tissue or bony sarcomas
- **SAVAC** revised (reference to SAVIM replaced with SAIME): Adjuvant therapy for newly diagnosed Ewing's sarcoma/peripheral neuroectodermal tumor (PNET) or rhabdomyosarcoma using vincristine, adriamycin and cyclophosphamide (this is alternated with SAIME)
- **SAVACM** revised (reference to SAVIM replaced with SAIME): Therapy for newly diagnosed Ewing's sarcoma/peripheral neuroectodermal tumor (PNET) and rhabdomyosarcoma with pelvic primaries or chemotherapy induced hematuria using vincristine, doxorubicin (Adriamycin®) and cyclophosphamide SAVACM is alternated with SAIME)
- **SAVIM** deleted (replaced by SAIME): Etoposide, ifosfamide-mesna for patients with newly diagnosed Ewing's sarcoma/peripheral

- neuroectodermal tumor (PNET) or rhabdomyosarcoma or advanced sarcomas
- **SMAJLEV** revised (contact physician): Adjuvant therapy for high risk malignant melanoma using levamisole
  - **SMCCNU** revised (contact physician): Palliative therapy for metastatic melanoma using lomustine (CCNU)
  - **SMDD** revised (contact physician): Palliative Therapy for metastatic malignant melanoma using cisplatin and dacarbazine (DTIC)
  - **SMDTIC** revised (contact physician): Palliative therapy for metastatic malignant melanoma using high dose dacarbazine (DTIC)
  - **SMILBCG** revised (contact physician): standard protocol – intralesional BCG
  - **SMTAM** revised (contact physician): Palliative therapy for malignant melanoma using tamoxifen
  - **SMTV** revised (contact physician): Second line treatment of metastatic malignant melanoma using tamoxifen and vinblastine
  - **SCHYPICAL** revised (preparation of zoledronic acid, treatment for  $\text{Ca}^{2+} < 3.5$  mmol): Guidelines for the diagnosis and management of malignancy related hypercalcemia

Protocols are available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols.

### CANCER MANAGEMENT MANUAL

The Cancer Management Manual is available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Cancer Management Guidelines.

### PRE-PRINTED ORDER UPDATE

Pre-printed orders should always be checked with the most current BC Cancer Agency protocol summaries. The BC Cancer Agency Vancouver Centre has prepared chemotherapy pre-printed orders, which can be used as a guide for reference. An index to the orders can be obtained by Fax-back.

- **BRAJCEF** revised (appointment time): Adjuvant therapy for breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRAJCEFG** revised (appointment time): Adjuvant therapy for breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- **BRINFCEF** revised (appointment time): Therapy for inflammatory breast cancer using cyclophosphamide, epirubicin and fluorouracil

- **BRINFCEFG** revised (appointment time): Therapy for inflammatory breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- **BRLACEF** revised (appointment time): Therapy for locally advanced breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRLACEFG** revised (appointment time): Therapy for locally advanced breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- **SAVACM** revised (typo corrected for maximum dose for vincristine): Therapy for newly diagnosed Ewing's sarcoma/peripheral neuroectodermal tumor (PNET) and rhabdomyosarcoma with pelvic primaries or chemotherapy induced hematuria using vincristine, doxorubicin (Adriamycin®) and cyclophosphamide

### PATIENT EDUCATION

Patient information handouts for cancer drugs are available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Drug Database, Drug Information for the Patient.

Protocol-specific patient information handouts are available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols, Information for the Patient.

### CANCER DRUG MANUAL

The Cancer Drug Manual is available on the BC Cancer Agency website [www.bccancer.bc.ca/cdm/](http://www.bccancer.bc.ca/cdm/).

### PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

BC Cancer Agency Systemic Therapy Policies are available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols, Policies and Procedures.

### FOCUS ON THE ROLE OF BISPHTHONATES THERAPY IN THE TREATMENT OF BONE METASTASES

Bone metastases can be a common occurrence in patients with metastatic cancer, particularly in cancer of the breast, prostate, and lung.<sup>1</sup> In the healthy individual, normal bone undergoes

continual remodeling in which the resorption of old bone by osteoclasts (osteolysis) is balanced by the formation of new bone by osteoblasts (osteogenesis). When tumour cells metastasize to bone, this normal balance can become upset, leading to either excess bone resorption or excess bone formation depending on the tumour type from which the metastasis occurred.

Osteolytic metastases can be characterized by increased osteoclast activity, excessive bone resorption, and bone destruction. Growth factors and proteins released during osteoclastic bone resorption are believed to interact with the tumour cells to promote local tumour growth. The tumour cells, in turn, release mediators that further stimulate osteoclastic activity resulting in a repetitious cycle of bone resorption and tumour growth.<sup>3</sup>

These osteolytic bone lesions will place the patient at greater risk for numerous morbidities such as bone pain, fractures, spinal cord compression, and malignancy-related hypercalcemia.<sup>2,4</sup> Conversely, osteoblastic bone lesions stimulate osteogenesis. This increase in bone formation will eventually lead to an increase in osteoclast activity in order to try and balance the effect. As a result, increases in osteolytic activity, and hence morbidities similar to those with osteolytic disease, will eventually be observed in patients with osteoblastic metastases.<sup>5</sup>

The type of metastatic bone lesion observed in patients depends upon the source of the primary tumour. Bone metastases arising from breast cancer, for example, may exhibit osteolytic, osteoblastic, or mixed lesions – with osteolytic being the predominant form.<sup>1</sup> In contrast, bone lesions in prostate cancer patients are primarily of the osteoblastic type; however osteolytic lesions may also occur.<sup>1,5</sup> Bone metastases from primary lung cancers usually produce osteolytic lesions<sup>1</sup> and in multiple myeloma, the bone lesions are entirely osteolytic.<sup>6,7</sup> The type of lesion notwithstanding, bone resorption – and ultimately the osteoclast – has been targeted as a key area of therapy for the treatment of skeletal metastases regardless of the origin of the primary tumour.

Treatment of metastatic bone disease remains primarily palliative. The direct anti-tumour effects of systemic therapy (i.e., chemotherapy and hormone therapy) as well as radiation therapy for the relief of pain and prevention of fracture are the standard therapies available. The prevention or delay in osteoclast-mediated bone resorption has become another area in which the treatment of

certain types of bone metastases may be achieved. The standard of therapy for this purpose has become the use of bisphosphonates.

### **Bisphosphonates**

The bisphosphonates are analogues of naturally occurring pyrophosphate, which adsorb strongly to hydroxyapatite at sites of active bone remodeling. They inhibit osteoclast function in both normal and diseased bone by reducing the osteoclast population as well as inhibiting their activity.<sup>8-10</sup> The various proposed mechanisms of action include: inhibition of osteoclast production,<sup>8</sup> induction of apoptosis (programmed cell death),<sup>11,12</sup> and modification of the cell environment.<sup>8,13</sup> Some bisphosphonates form cytotoxic ATP analogs (clodronate),<sup>12</sup> while others interfere with the osteoclast metabolic pathway (pamidronate, zoledronic acid).<sup>14</sup>

### **Clodronate**

Several smaller clinical trials have investigated the use of clodronate in the treatment of bone metastases secondary to breast and prostate cancers. In two earlier randomized, controlled studies in breast cancer patients with bone metastases, an objective clinical benefit in primary endpoints was observed; however these findings either lacked the statistical power to show significance<sup>19</sup> or the method of statistical analysis was found to be questionable.<sup>20</sup> The findings of a more recent randomized trial involving 100 breast cancer patients treated with either oral clodronate or no additional therapy were shown to be more conclusive and positive. It was demonstrated that the time to first skeletal related event (SRE) was significantly longer in the group receiving clodronate than in the group receiving no additional therapy (25% of patients having an SRE at 19 months vs. 4 months for the no-treatment arm).<sup>21</sup> In several randomized, placebo-controlled studies in patients with prostate cancer, clodronate failed to show a significant benefit in objective or subjective endpoints (e.g., pain relief, palliative response).<sup>22,23</sup>

### **Pamidronate**

In a number of randomized, multicentre, placebo-controlled trials involving over 1,500 patients with predominantly osteolytic-type bone metastases secondary to breast cancer and multiple myeloma, a significant and objective clinical benefit was demonstrated in those receiving pamidronate therapy.<sup>15-17</sup> In one study, a significant increase in the median time to first SRE was reported for breast cancer patients with bone metastases receiving

pamidronate – 13 months vs. 7 months when compared to placebo. There was also a significant reduction in the proportion of patients who experienced an SRE at 24 months (56% vs. 67% compared to placebo),<sup>16</sup> showing the potential long-term benefits of pamidronate in this population. A separate randomized, controlled study investigating the efficacy of pamidronate in patients with advanced multiple myeloma showed a significant clinical benefit in those receiving pamidronate. It was observed that there was a significant reduction in the mean number of SRE's in the pamidronate-arm (1.3 vs. 2.2 when compared to placebo), as well as a reduction in the proportion of patients who experienced an SRE during the 21-month follow-up. It was further noted that pamidronate as an adjunct to chemotherapy may also improve the survival of these patients depending on the type of chemotherapy they may receive concurrently.<sup>17</sup> In a randomized, placebo-controlled study of 236 patients with bone metastases arising from advanced prostate cancer, pamidronate failed to show a significant benefit. After 6 months of therapy there was no significant reduction in the proportion of patients with an SRE or bone pain in the pamidronate-arm when compared to placebo.<sup>18</sup>

### Zoledronic acid

In several randomized, controlled, multicentre trials involving over 1,500 patients with bone metastases secondary to breast cancer, multiple myeloma, prostate cancer, and other solid tumours, the use of zoledronic acid has been observed to be of clinical benefit.<sup>24-26</sup> One randomized, double-blind trial evaluated the efficacy of different doses for zoledronic acid (0.2, 2, or 4 mg) compared to pamidronate (90 mg) in 280 patients with osteolytic lesions from metastatic breast cancer or multiple myeloma. It was observed that zoledronic acid doses of 2 and 4 mg were at least as effective in treating osteolytic lesions as compared to 90 mg of pamidronate.<sup>24</sup>

Another trial evaluated the efficacy and safety of zoledronic acid compared to pamidronate in 766 breast cancer patients with osteolytic, mixed, or osteoblastic bone metastases. The proportion of patients with an SRE after 13 months (primary endpoint) in the zoledronic acid group was 43% (comparable to 45% for the pamidronate-arm). The median time to first SRE (a secondary endpoint) was almost identical at 1 year for both treatment arms.<sup>25</sup> No significant difference in these two primary endpoints was seen after 25 months of follow-up, although zoledronic acid 4 mg was

associated with a small decrease in the risk of developing any SRE (hazard ratio 0.82, 95% CI 0.67-0.99,  $p = 0.04$ ).<sup>25a</sup>

In a more recent randomized, double-blind, multicentre trial of 643 patients with bone metastases secondary to hormone-refractory prostate cancer, zoledronic acid (4 mg or 8 mg) was compared to placebo. Of note, some patients in the 8 mg zoledronic acid arm experienced renal dysfunction and were subsequently dose-reduced to 4 mg of zoledronic acid. This group was referred to as 8/4 mg zoledronic acid arm. It was observed that the proportion of patients having at least one SRE (the primary endpoint) was significantly lower in the 4 mg zoledronic acid group compared to placebo (33.2% vs. 44.2% respectively). However, no statistically significant difference was seen with the 8/4 mg zoledronic acid group (38.5%) when compared to placebo. Similar results were observed when comparing the median time to first SRE between groups: at least 420 days in patients receiving 4 mg zoledronic acid compared to 321 days in the placebo arm ( $P = 0.01$ ); and 363 days for those patients in the 8/4 mg zoledronic acid group (not statistically significant).<sup>26</sup>

In a review of this study, by Canil and Tannock, it was noted that, “several features of the study should lead to caution in accepting this result as sufficient evidence to introduce zoledronic acid into standard practice for the treatment of patients with metastatic prostate cancer.” Firstly, statistical power of the study was lost to some degree when the investigators failed to include patients from the 8/4 mg zoledronic arm in their revised analysis. Secondly, the fact that the combined 8/4 mg zoledronic acid arm should have shown at least comparable results to the 4 mg zoledronic acid arm but did not (no significant difference as compared to placebo) weakens the results. Lastly, the incidence of a number of side effects was higher in both treatment arms when compared to those patients receiving placebo – the investigators reported the zoledronic acid was, “well-tolerated.” They therefore concluded that the study has not, “provided a clear demonstration of net therapeutic effect.”<sup>27</sup>

Bisphosphonate therapy has been the standard of care for patients with breast cancer, multiple myeloma, and primarily osteolytic bone lesions, resulting in a decreased risk of skeletal events and an improvement in quality of life. Currently, two bisphosphonates – clodronate and pamidronate – are listed on the BCCA's Benefit Drug List, both of which require the completion of a Class 2 Drug

Registration Form. Oral clodronate is indicated first-line for the treatment of bone metastases in breast cancer; however for patients unable to tolerate oral clodronate, IV pamidronate or IV clodronate may be used (BRAVCLOD Protocol). [Note: There are other BCCA protocols employing bisphosphonate therapy; however the BRAVCLOD Protocol is the only one currently utilized specifically for the *treatment* of bone metastases].

In consideration of the available literature and the recent debate surrounding the use of zoledronic acid in the treatment of prostate cancer metastatic to bone, the BCCA does not currently fund the use of bisphosphonate therapy for the treatment of bone metastases in prostate cancer patients.

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#### LIBRARY/CANCER INFORMATION CENTRE

**Unconventional Cancer Therapies Manual** is available on the BC Cancer Agency website [www.bccancer.bc.ca](http://www.bccancer.bc.ca) under Patient/Public Info, Unconventional Therapies. The manual consists of 46 short monographs on the more commonly used unconventional cancer therapies (e.g., Essiac, vitamins, teas, shark cartilage) and includes tips for the patient and family on how unconventional therapies can be evaluated. For each therapy the manual provides proponent/advocate claims, as well as evidence-based evaluation/critique quotations from the literature.

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| SAVIM                                | SMAJLEV  | SMCCNU   |
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| <input type="checkbox"/> SAVACM   |                                   |                                   |
| Protocol Summaries: (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )           |                                   |                                   |
| Index of Protocol Summaries   | <input type="checkbox"/> Index_NT | <input type="checkbox"/> Index_W6 |
| <input type="checkbox"/> LYHDMTXP   | <input type="checkbox"/> LYHDMTXR | <input type="checkbox"/> OSVIM    |
| <input type="checkbox"/> SAIME  | <input type="checkbox"/> SAVAC    | <input type="checkbox"/> SAVACM   |
| <input type="checkbox"/> SAVIM  | <input type="checkbox"/> SMAJLEV  | <input type="checkbox"/> SMCCNU   |
| <input type="checkbox"/> SMDD   | <input type="checkbox"/> SMDTIC   | <input type="checkbox"/> SMILBCG  |
| <input type="checkbox"/> SMTAM  | <input type="checkbox"/> SMTV     | <input type="checkbox"/> SCHYPCAL |
| Provincial Systemic Therapy Program Policies  |                                   |                                   |
| Reimbursement (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )                 |                                   |                                   |
| <input type="checkbox"/> Benefit Drug List (01 Mar 2003)  |                                   |                                   |
| <input type="checkbox"/> Class 2 Form (01 Mar 2003)   |                                   |                                   |
| Systemic Therapy Update Index (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> ) |                                   |                                   |
| <input type="checkbox"/> Jan-Dec 2000   |                                   |                                   |
| <input type="checkbox"/> Jan-Dec 2001   |                                   |                                   |
| <input type="checkbox"/> Jan-Dec 2002   |                                   |                                   |