

Systemic Therapy Update

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For Health Professionals Who Care for People with Cancer

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New Programs

BC Cancer Provincial Systemic Therapy has approved the following new treatment programs effective 01 June 2025. Full details of all treatment programs are available in the <u>Chemotherapy Protocols</u> section of the BC Cancer website.

Genitourinary

Lutetium (¹⁷⁷Lu) Vipivotide Tetraxetan for Metastatic Castration-Resistant Prostate Cancer (UGUPLVT) – The BC Cancer Genitourinary Tumour Group is implementing treatment with ¹⁷⁷Lu vipivotide tetraxetan (PLUVICTO) for patients with metastatic castration-resistant prostate cancer (mCRPC) whose cancer has progressed on an androgen receptor pathway inhibitor (ARPI) and at least one prior taxane-based chemotherapy regimen. Patients must have a prostate-specific membrane antigen (PSMA)-positive lesion. PSMA is a transmembrane glycoprotein that is highly expressed in prostate cancer cells. ¹⁷⁷Lu vipivotide tetraxetan contains the radionuclide lutetium-177 linked to a targeting moiety that binds to PSMA.¹ Upon the binding of ¹⁷⁷Lu vipivotide tetraxetan to PSMA-expressing cancer cells, therapeutic radiation from ¹⁷⁷Lu is delivered to the targeted cells, as well as to surrounding cells. This induces DNA damage, which can lead to cell death. Treatment with ¹⁷⁷Lu vipivotide tetraxetan is by IV infusion every six weeks, to a maximum of six doses. The management of adverse effects such as hematologic or renal toxicity is outlined in the

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treatment protocol, and may include temporary dose interruption, dose reduction or permanent discontinuation. BC Cancer Compassionate Access Program (CAP) approval is required.

Approval for this new treatment program is based principally on the phase III, randomized, controlled VISION trial, which compared treatment with ¹⁷⁷Lu vipivotide tetraxetan in combination with best supportive care or best standard of care (BSC-BSoC) with BSC-BSoC alone.² The trial demonstrated that treatment with ¹⁷⁷Lu vipivotide tetraxetan in patients with progressive PSMA-positive mCRPC who had previously received at least one ARPI and one taxane-based regimen resulted in a clinically meaningful improvement in overall survival.

Myeloma

Teclistamab for Treatment of Relapsed and Refractory Multiple Myeloma (UMYTEC) – The BC Cancer Lymphoma and Myeloma Tumour Group is implementing teclistamab for patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or intolerance to their last therapy. Teclistamab is a bispecific T-cell engager that targets B cell maturation antigen (BCMA) expressed on multiple myeloma cells and CD3 receptors expressed on T cells. Teclistamab is administered subcutaneously, and a step-up dosing regimen is followed for the first cycle. Cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) have been reported with teclistamab, requiring inpatient treatment for at least the first three administrations of teclistamab. BC Cancer Compassionate Access Program (CAP) approval is required.

The phase I/II single-arm MajesTEC-1 study evaluated teclistamab therapy in patients with multiple myeloma who were relapsed or refractory to established therapies.^{3,4} The study demonstrated that treatment with teclistamab may result in benefits in clinical response rates, overall survival and progression-free survival. Toxicities relating to teclistamab include CRS, ICANS, cytopenias and infections.

Skin & Melanoma

Ipilimumab and Nivolumab for Neoadjuvant Treatment of Stage III Melanoma (SMNAIPNI) – The BC Cancer Skin and Melanoma Tumour Group is introducing neoadjuvant ipilimumab and nivolumab for patients presenting with clinical stage III melanoma with planned standard curative intent resection. In this new treatment program, patients receive two cycles of ipilimumab and nivolumab, followed by repeat imaging and surgical resection. Further adjuvant treatment is guided by pathological response and BRAF mutation status. Patients with a major pathological response receive no further adjuvant treatment. Patients with non-major pathological response receive an additional 11 cycles of adjuvant treatment according to BRAF mutation status (dabrafenib-trametinib [SMAJDT] for BRAF-mutated or nivolumab [SMAJNIV4] for BRAF wild-type).

Approval of this treatment program is supported by the phase III, randomized, controlled NADINA trial.^{5,6} Patients with resectable stage III melanoma were randomized to two cycles of neoadjuvant ipilimumab and nivolumab followed by surgery, or surgery followed by 12 cycles of adjuvant nivolumab. In the neoadjuvant group, patients with a major pathological response did not receive any adjuvant treatment, and patients with a pathological partial response or nonresponse received adjuvant ipilimumab-nivolumab or dabrafenib-trametinib for up to one year. Overall, neoadjuvant ipilimumab and nivolumab followed by surgery and response-driven adjuvant therapy resulted in longer event-free survival than surgery followed by adjuvant nivolumab.

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References:

- 1. CADTH Reimbursement Recommendation. Lutetium (¹⁷⁷Lu) Vipivotide Tetraxetan (Pluvicto[®]). Canadian Journal of Health Technologies 2023;3(3):1-26.
- Sartor O, de Bono J, Chi KN, et al. Lutetium-177–PSMA-617 for metastatic castration-resistant prostate cancer. N Engl J Med 2021;385(12):1091-1103. <u>https://doi.org/10.1056/NEJMoa2107322</u>
- 3. CADTH Reimbursement Recommendation. Teclistamab (Tecvayli®). Canadian Journal of Health Technologies 2024;4(4):1-37. https://doi.org/10.51731/cjht.2024.874
- 4. Usmani SZ, Garfall AL, van de Donk NWCJ, et al. Teclistamab, a B-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC-1): a multicentre, open-label, single-arm, phase 1 study. Lancet 2021;398(10301):665-674. https://doi.org/10.1016/S0140-6736(21)01338-6
- Canada's Drug Agency (CDA-AMC) Reimbursement Recommendation. Nivolumab (Opdivo[®]) and Ipilimumab (Yervoy[®]). <u>https://www.cda-amc.ca/sites/default/files/DRR/2025/PX0371_FMEC_Recommendation.pdf</u>
- Blank CU, Lucas MW, Scolyer RA, et al. Neoadjuvant nivolumab and ipilimumab in resectable stage III melanoma. N Engl J Med 2024;391(18): 1696-1708. <u>https://doi.org/10.1056/NEJMoa2402604</u>

Expansion of Existing Programs

BC Cancer Provincial Systemic Therapy has approved the expansion of the following treatment program effective 01 June 2025.

Breast

Sacituzumab Govitecan for Palliative Therapy of Metastatic Breast Cancer (BRAVSG) – The BC Cancer Breast Tumour Group is expanding the eligibility criteria to include patients with hormone receptor (HR)-positive, HER2-negative, locally advanced unresectable or metastatic breast cancer. This expansion is supported by data from the phase III, open-label, randomized TROPiCS-02 trial which demonstrated a statistically significant improvement in progression-free survival and overall survival compared with physician's choice chemotherapy (i.e., eribulin, capecitabine, gemcitabine or vinorelbine).^{1,2,3} Full eligibility criteria are outlined in the treatment protocol.

References:

- 1. CADTH Reimbursement Recommendation. Sacituzumab govitecan (Trodelvy®). Canadian Journal of Health Technologies 2024;4(2):1-30. https://doi.org/10.51731/ciht.2024.875
- 2. Rugo HS, Bardia A, Marmé F, et al. Sacituzumab govitecan in hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer. *J Clin Oncol* 2022;40(29):3365-3376. <u>https://doi.org/10.1200/JCO.22.01002</u>
- 3. Rugo HS, Bardia A, Marmé F, et al. Overall survival with sacituzumab govitecan in hormone receptor-positive and human epidermal growth factor receptor 2-negative metastatic breast cancer (TROPiCS-02): a randomised, open-label, multicentre, phase 3 trial. *Lancet* 2023;402(10411):1423-1433. <u>https://doi.org/10.1016/S0140-6736(23)01245-X</u>

Cancer Drug Manual[©]

All documents are available in the <u>Cancer Drug Manual</u>[©] on the BC Cancer website.

Revised Documents

Daunorubicin Patient Handout

Throughout: updated per current template language

Doxorubicin Patient Handout

Throughout: updated per current template language

Cancer Drug Manual[©]

Doxorubicin Pegylated Liposomal Patient Handout

Throughout: updated per current template language

Epirubicin Patient Handout

Throughout: updated per current template language

Idarubicin Patient Handout

Throughout: updated per current template language

Mitoxantrone Patient Handout

Throughout: updated per current template language

Plerixafor Monograph

Cautions (Fertility): updated to include information about detectability in ovaries Cautions (Pregnancy): updated to include suspected mechanism for developmental toxicity and recommendations regarding pregnancy and contraception Supply and Storage: added new brand (Jamp) Dosage Guidelines: added fixed-dose for patient weight less than or equal to 83 kg and updated regimen

for patient weight greater than 83 kg; added dosing in children

Teclistamab Monograph and Patient Handout

Header and Footer: removed "interim" designation

Solution Preparation and Compatibility: updated instructions related to closed system transfer devices Parenteral Administration: added new protocol UMYTEC and bolded/italicized BC Cancer standard administration

Dosage Guidelines: added new protocol UMYTEC and bolded/italicized BC Cancer standard dosing *Patient Handout:* removed "interim" designation from Header/Footer

Chemotherapy Preparation and Stability Chart

Plerixafor: added new brand (Jamp) Teclistamab: updated volume cutoff for closed system transfer devices in Special Precautions column Zoledronic Acid: added new brand (Taro)

Continuing Education

Family Practice Oncology Network

The Family Practice Oncology Network (FPON) is pleased to announce a webinar session on **The Role of Diet and Exercise in Cancer Treatment and Survivorship** with Dr. Thomas Hedley, on Thursday 19 June 2025, 8 am to 9 am, as part of the Complimentary Accredited Webinar Series.

By the end of the session, participants will be able to:

- Describe the impact of diet and exercise interventions on cancer-related outcomes for patients on systemic therapy or active surveillance
- Review exercise recommendations for cancer survivors
- Cite the impact of post-diagnosis dietary patterns on cancer and other health-related outcomes for cancer survivors

For more information and link to registration, visit: <u>FPON Webinar: The Role of Diet and Exercise in Cancer Treatment and Survivorship | Course | UBC CPD</u>

Benefit Drug List

New Programs

The following treatment programs have been added to the BC Cancer <u>Benefit Drug List</u> effective 01 June 2025:

Protocol Title	Protocol Code	Benefit Status
Treatment of Metastatic Castration-Resistant Prostate Cancer using Lutetium (177Lu) Vipivotide Tetraxetan (PLUVICTO)	UGUPLVT	Restricted
Treatment of Relapsed and Refractory Multiple Myeloma using Teclistamab	UMYTEC	Restricted
Neoadjuvant Treatment of Stage III Melanoma using Ipilimumab and Nivolumab	SMNAIPNI	Class I

Revised Programs

The following treatment program has been revised on the BC Cancer <u>Benefit Drug List</u> effective 01 June 2025:

Protocol Title	Protocol Code	Benefit Status
Lymphoma Palliative Chemotherapy (lomustine has been deleted from LYPALL on the Benefit Drug List, to align with its previous removal as an option in the LYPALL treatment protocol)	LYPALL	Class I

Highlights of New & Revised Protocols, PPPOs and Patient Handouts

BC Cancer 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, with document revisions indicated in the respective columns. Protocol codes for treatment requiring BC Cancer Compassionate Access Program (CAP) approval are prefixed with the letter **U**.

NEW Protocols, PPPOs and Patient Handouts (new documents checked 🗹)

Protocol Code	Protocol Title	Protocol	РРРО	Handout
UGUPLVT	Treatment of Metastatic Castration-ResistantProstate Cancer using Lutetium (177Lu) VipivotideTetraxetan (PLUVICTO)		V	
UMYTEC	eatment of Relapsed and Refractory Multiple veloma using Teclistamab			
SMNAIPNI	NAIPNI Neoadjuvant Treatment of Stage III Melanoma using Ipilimumab and Nivolumab Image: Comparison of the stage in t			

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)

Protocol Code	Protocol Title	Protocol	РРРО	Handout	
BR Breast	BR Breast				
BRAVSG	Palliative Therapy for Metastatic Breast Cancer using Sacituzumab Govitecan	Title, eligibility, exclusions, tests, physician phone contact and references updated, minor formatting			
GO Gynecolog	ical				
GOCABR	Alternative Treatment of Gynecological Malignancies using Carboplatin and Paclitaxel NAB (ABRAXANE)	Eligibility and contact info updated			
GOCISP	Alternative Treatment of Gynecological Malignancies using Cisplatin and Paclitaxel	Reference to GOENDCAT removed and contact info updated			
GOENDCAD	Treatment of Primary Advanced or Recurrent Endometrial Cancer using Carboplatin and Docetaxel	Relative contraindications and contact info updated			
GOSADG	Treatment of Uterine Sarcoma Cancer using Docetaxel and Gemcitabine	Eligibility and contact info updated			
GU Genitourir	GU Genitourinary				
GUPADT	Androgen Deprivation Therapy for Prostate Cancer		page numbers added		

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)

Protocol Code	Protocol Title	Protocol	РРРО	Handout	
SM Skin & Me	SM Skin & Melanoma				
SMAJDT	Treatment of Stage III and IV, BRAF mutated, fully resected Melanoma Using daBRAFenib	Eligibility, exclusions, tests and treatment updated			
SMAJNIV	Adjuvant Treatment of Resected Stage III-IV NED Melanoma using Nivolumab	Eligibility and treatment updated			
SMAJNIV4	Treatment of Resected Melanoma using 4-Weekly Nivolumab	Eligibility, exclusions and treatment updated		Treatment summary updated	
SMAJPEM	Adjuvant Treatment of Resected Stage IIB to IV NED Melanoma using Pembrolizumab	Eligibility updated			
SMAJPEM6	Adjuvant Treatment of Resected Stage IIB to IV NED Melanoma using 6-Weekly Pembrolizumab	Eligibility updated			
SMAVALIPNI	Treatment of Unresectable or Metastatic Melanoma using Alternative Dosing Regimen of Ipilimumab and Nivolumab	Eligibility and exclusions updated			
SMAVIPNI	Treatment of Unresectable or Metastatic Melanoma using Ipilimumab and Nivolumab	Eligibility and tests updated			
SMNAPEM	Neoadjuvant-Adjuvant Treatment of Stage IIIB to IV Melanoma using Pembrolizumab	Eligibility and exclusions updated			

Resources and Contact Information

Resource	Phone	Email / Toll Free / Fax		
Systemic Therapy Update: www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/systemic-therapy-update				
Systemic Therapy Update Editor	604-877-6000 x 672649	bulletin@bccancer.bc.ca		
Oncology Drug Information	604-877-6275	druginfo@bccancer.bc.ca		
Cancer Drug Manual Editor	250-519-5500 x 693742	<u>nbadry@bccancer.bc.ca</u>		
Pharmacy Oncology Certification	250-712-3900 x 686820	rxchemocert@bccancer.bc.ca		
CAP – Compassionate Access Program	604-877-6277	<u>cap_bcca@bccancer.bc.ca</u> fax_604-708-2026		
OSCAR – Online System for Cancer Drugs Adjudication and Reimbursement	888-355-0355	oscar@bccancer.bc.ca fax 604-708-2051		
Library/Cancer Information	604-675-8003	toll free 888-675-8001 x 8003 requests@bccancer.bc.ca		
Library Document Delivery	604-675-8002	requests@bccancer.bc.ca		
Pharmacy Professional Practice	604-877-6000 x 672247	mlin@bccancer.bc.ca		
Professional Practice, Nursing	604-877-6000 x 672623	BCCancerPPNAdmin@phsa.ca		
Provincial Systemic Therapy Network	604-877-6000 x 672247	ProvincialSystemicOffice@bccancer.bc.ca		
BC Cancer – Abbotsford	604-851-4710	toll free 877-547-3777		
BC Cancer – Kelowna	250-712-3900	toll free 888-563-7773		
BC Cancer – Prince George	250-645-7300	toll free 855-775-7300		
BC Cancer – Surrey	604-930-2098	toll free 800-523-2885		
BC Cancer – Vancouver	604-877-6000	toll free 800-663-3333		
BC Cancer – Victoria	250-519-5500	toll free 800-670-3322		

Community Oncology Network (CON) sites: To update your contact information, please contact: <u>bulletin@bccancer.bc.ca</u>

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