



For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

NEW PROGRAMS

The BCCA Provincial Systemic Therapy Program has approved the following new program effective 1 June 2016:

Melanoma:

Pembrolizumab for Unresectable or Metastatic Melanoma (USMAVPEM) – Pembrolizumab is a programmed cell death 1 (PD-1) receptor inhibitor that is active in unresectable metastatic melanoma regardless of BRAF mutation status. It is given as an intravenous (IV) infusion every three weeks until disease progression, or for a maximum of 24 months. Patients with any BRAF mutation status melanoma are eligible for pembrolizumab if they have not previously received ipilimumab.

Approval of this new treatment program at the BCCA is based on the KEYNOTE-006 trial, an open-label, three-armed, randomized controlled trial that compared pembrolizumab with ipilimumab in patients with advanced melanoma.¹ The 1-year overall survival was superior with pembrolizumab compared to ipilimumab (68.4% vs. 58.2%, respectively) [hazard ratio 0.69 (95% CI 0.52-0.90)]. The median OS was not reached in any of the treatment arms. The median progression free survival (PFS) was also superior for

EDITOR'S CHOICE

pembrolizumab (4.1 months vs. 2.8 months, respectively). For information about pembrolizumab's pharmacology and toxicities, please see the Cancer Drug Manual section below.

For ALL NEW patients who meet the USMAVPEM protocol eligibility criteria, a BCCA Compassionate Access Program (CAP) approval is REQUIRED.

Patients who were previously enrolled in the MERCK CARE® Oncology Patient Assistance Program prior to 1 June 2016, and who will be transitioned to treatment at the BCCA will be REQUIRED to submit a CAP approval. CON patients who were previously enrolled in the MERCK CARE® Oncology Patient Assistance Program will NOT be required to submit a CAP approval. For further information, please contact the MERCK CARE® Oncology Patient Assistance Program.

References:

1. Robert C, Schachter J, Long GV, et al. Pembrolizumab versus ipilimumab in advanced melanoma. NEJM 2015;372(26):2521-2532.

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

The **Pembrolizumab Monograph** and **Patient Handout** have been developed with expert review provided by Dr. Kerry Savage (Medical Oncologist) and Robert Tillmanns (Pharmacist) from the BCCA Melanoma Tumour Group. Pembrolizumab is a selective, humanized IgG monoclonal antibody that inhibits PD-1 receptors from binding to ligands expressed on antigen presenting or tumour cells. It re-stimulates tumour-specific cytotoxic T lymphocytes and reactivates anti-tumour immunity.

Pembrolizumab-associated side effects include fatigue, pruritus, rash, diarrhea, and arthralgia. Less common, but more severe immune-related adverse reactions include pneumonitis, hepatitis, hypophysitis, colitis, nephritis, and thyroiditis. These side effects can be severe and potentially fatal if not treated promptly. Severe immune-related adverse reactions may require withholding or permanently discontinuing treatment, and initiating the appropriate supportive care medications. Patients must be strongly advised to report all toxicities and to not self-manage without medical advice.

Siltuximab Interim Monograph has been developed. Siltuximab is a chimeric IgG monoclonal antibody used in the treatment of multi-centric Castleman's disease. The recommended dosing is 11 mg/kg administered IV every three weeks. Infusion-related reactions can occur in approximately 8% of cases, but anaphylaxis is rare. Symptoms of infusion-related reactions include pruritus, erythema, chest pain and nausea. Infusions may be resumed at a lower rate following resolution of symptoms, and future cycles may warrant premedications with antihistamines, acetaminophen and corticosteroids. Siltuximab is not a BCCA Benefit Drug.

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Cisplatin Monograph

- *Side Effects section* – Venous thromboembolism has been added as per a recent Health Canada Safety Review; information on hydration in children has been updated under *Nephrotoxicity*

BENEFIT DRUG LIST

NEW PROGRAMS

The following programs have been added to the BCCA [Benefit Drug List](#) effective 1 June 2016:

Protocol Title	Protocol Code	Benefit Status
SAIME Alternating with SAVAC or SAVACM with Filgrastim Support at a <u>TWO</u> Weekly Interval for Newly Diagnosed Ewing's Sarcoma/ Ewing's Family of Tumours, Desmoplastic Intra-Abdominal Small Round Blue Cell Tumour or Rhabdomyosarcoma	SAALT2W	Class I
SAIME Alternating with SAVAC or SAVACM with Filgrastim Support at a <u>THREE</u> Weekly Interval for Newly Diagnosed Ewing's Sarcoma/ Ewing's Family of Tumours, Desmoplastic Intra-Abdominal Small Round Blue Cell Tumour or Rhabdomyosarcoma	SAALT3W	Class I
Treatment of Unresectable or Metastatic Melanoma using Pembrolizumab	USMAVPEM	Restricted

REVISED PROGRAMS

The following programs have been reclassified from **Class II** to **Class I** status on the BCCA [Benefit Drug List](#) effective 1 June 2016:

Adult Treatment Programs:	
Protocol Code	Protocol Title
CNAJZRT	Concomitant and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas
CNTEMOZ	Therapy for Malignant Brain Tumours Using Temozolomide
CNTEMOZMD	Therapy for Malignant Brain Tumours using Metronomic Dosing of Temozolomide
CNTEM60	Therapy for Newly Diagnosed Malignant Brain Tumours with MGMT Methylation in Elderly Patients using Temozolomide
GIAVTZCAP	Palliative Therapy of Metastatic Neuroendocrine Cancer Using Temozolomide and Capecitabine
HLHETCSPA	Treatment of Hemophagocytic Lymphohistiocytosis with Etoposide, Dexamethasone and cycloSPORINE
HNOTAMIRT	Radioprotection in Head and Neck Radiation using Amifostine
LKANAG	Anagrelide as second-line treatment of thrombocytosis related to myeloproliferative disorders
LYALEM	Treatment with Subcutaneous or Intravenous Alemtuzumab for Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) or with Intravenous Alemtuzumab for Previously Untreated T-Prolymphocytic Leukemia (T-PLL)
LYCSPA	Cyclosporine for cytopenias associated with lymphoproliferative disorder of large granular lymphocytes
SMAVTMZ	Palliative Therapy for Malignant Melanoma with Brain Metastases Using Temozolomide

BENEFIT DRUG LIST

Pediatric Treatment Programs:	
Treatment	Indication
Aldesleukin	High Risk Neuroblastoma (ANBL0032 Study)
Dexrazoxane	Neuroblastoma (CCG AEW51031)
	Rhabdomyosarcoma (COG ARST08P1)
Irinotecan	Intermediate-Risk Rhabdomyosarcoma (COG ARST0531)
	Recurrent Neuroblastoma (COG ANBL0421)
	High Risk Renal Tumors (COG AREN0321)
	High Risk Rhabdomyosarcoma (COG ARST0431)
	Rhabdomyosarcoma (COG ARST08P1)
	Recurrent/Refractory Medulloblastomas/CNS PNET (COG ACNS0821)
Rituximab	CD20 + PTLD Post-Solid Organ Transplantation (COG ANHL0221)
	Newly Diagnosed Advanced B-Cell Leukemia/Lymphoma (COG ANHL01P1)
Sargramostim	Neuroblastoma (COG ANBL0032)
	Relapsed Neuroblastoma (COG ANBL1021)
Temozolomide	Brain Tumours
	Recurrent Neuroblastoma (COG ANBL0421)
	Rhabdomyosarcoma (COG ARST08P1)

REMOVAL OF BENEFIT DRUGS FROM CLASS II FORM

The following drugs have been reclassified from Class II to Class I status and, therefore, removed from the BCCA Class II form effective 1 June 2016:

Aldesleukin Alemtuzumab Amifostine Anagrelide	Cyclosporine Dexrazoxane Irinotecan (pediatric use only) Rituximab (pediatric use only)	Sargramostim Temozolomide
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DELISTED PROGRAMS

The following pediatric treatment program has been removed from the [Benefit Drug List](#) effective 1 June 2016:

Treatment	Indication
Amifostine	Childhood Nasopharyngeal Carcinoma (COG ARAR0331)

SYSTEMIC THERAPY UPDATE EDITORIAL BOARD

WELCOME TO NEW BOARD MEMBER

The Systemic Therapy Update Editorial Board would like to welcome new board member, Lorraine Leitz, librarian from the BCCA Vancouver Island Centre (VIC). Lorraine has been the Reference Librarian at the BCCA VIC since March 2001. She has a Bachelor of Arts degree in English Literature and a Master of Library Science degree from the University of British Columbia. In addition to providing reference assistance to staff members, patients and family members on Vancouver Island, she maintains several resources on the BCCA website (including Recommended Websites and the Library Pathfinders), chairs the VIC Regional

SYSTEMIC THERAPY UPDATE EDITORIAL BOARD

Patient Education Group, and sits on several other committees and research teams related to patient education and patient information needs. Welcome, Lorraine!

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 treatment requiring BCCA Compassionate Access Program approval are prefixed with the letter “U”.

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

CODE	Protocol	PPPO	Patient Handout	Protocol Title
SAALT2W	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAIME Alternating with SAVAC or SAVACM with Filgrastim Support at a <u>TWO</u> Weekly Interval for Newly Diagnosed Ewing's Sarcoma/Ewing's Family of Tumours, Desmoplastic Intra-Abdominal Small Round Blue Cell Tumour or Rhabdomyosarcoma
SAALT3W	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAIME Alternating with SAVAC or SAVACM with Filgrastim Support at a <u>THREE</u> Weekly Interval for Newly Diagnosed Ewing's Sarcoma/Ewing's Family of Tumours, Desmoplastic Intra-Abdominal Small Round Blue Cell Tumour or Rhabdomyosarcoma
USMAVPEM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment of Unresectable or Metastatic Melanoma Using Pembrolizumab

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRLATWAC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment interval clarified</i>	NEOAdjuvant Therapy for Locally Advanced Breast Cancer Using Weekly PACLitaxel Followed by DOXOrubicin and Cyclophosphamide
GIAJCAP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Statement on hair loss clarified</i>	Adjuvant Therapy of Colon Cancer Using Capecitabine
GIAVCAP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Statement on hair loss clarified</i>	Palliative Therapy of Advanced Colorectal Cancer using Capecitabine
GICAPOX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin and Capecitabine

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
GICOXB	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Bevacizumab and Capecitabine
GIFFOX	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Fluorouracil, Leucovorin and Bevacizumab
GIFOLFOX	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Fluorouracil and Leucovorin
GIGAJCC	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Statement on hair loss clarified</i>	Adjuvant Chemotherapy of Gastric Cancer Patients with D2 Resection (Node Negative) or Ineligible for Adjuvant Chemoradiation, Using CISplatin and Capecitabine
GIGAJCPRT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Statement on hair loss clarified</i>	Adjuvant Chemotherapy of Gastric Cancer Patients with Completely Resected Gastric Cancer Using CISplatin and Capecitabine and Radiation Therapy
GIGAVCC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Protocol: cycle clarified; Handout: statement on hair loss clarified</i>	Palliative Therapy for Metastatic or Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma Using CISplatin and Capecitabine
GIRCAP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Statement on hair loss clarified</i>	Adjuvant Therapy for Stage II and III Rectal Cancer Previously Treated with Preoperative Radiation Therapy using Capecitabine
GIRCRT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Statement on hair loss clarified</i>	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma Using Capecitabine and Radiation Therapy
ULUAVAFAT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	First-Line Treatment of Epidermal Growth Factor Receptor Mutation-Positive Advanced Non-Small Cell Lung Cancer with Afatinib
ULUAVCRIZ	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Second-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer with Crizotinib
ULUAVCRIZF	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer with Crizotinib

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
LUAVDC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	First-Line Treatment of Advanced Non-Small Cell Lung Cancer with CISplatin and DOCEtaxel
LUAVDOC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer with DOCEtaxel
LUAVERL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Treatment of Advanced Non-Small Cell Lung Cancer with Erlotinib
ULUAVGEFF	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	First-Line Treatment of Epidermal Growth Factor Receptor Mutation-Positive Advanced Non-Small Cell Lung Cancer with Gefitinib
LUAVNP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Treatment for advanced non-small cell lung cancer with CISplatin and vinorelbine
LUAVPC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	First-Line treatment of advanced non-small cell lung cancer with CARBOplatin and PACLitaxel
LUAVPEM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer with Pemetrexed
LUAVPG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Treatment of advanced non-small cell lung cancer with platinum and gemcitabine
LUAVPP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	First-Line Treatment of Advanced Non-Small Cell Lung Cancer With Platinum and Pemetrexed
LUAVVIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Test requirements updated</i>	Treatment of Advanced Non-Small Cell Lung Cancer with Vinorelbine in Elderly Patients
SAAI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests and management of hematuria updated; aprepitant added to Premedications; mesna dilution volume updated</i>	Therapy for Advanced Soft Tissue Sarcoma using DOXOrubicin, Ifosfamide-Mesna
SAAJADIC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Title, dacarbazine dilution volume and infusion time updated</i>	Adjuvant Treatment of Patients with Soft Tissue Sarcoma using DOXOrubicin and Dacarbazine
SAAVADIC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Title, dacarbazine dilution volume and infusion time updated</i>	Treatment of Patients with Soft Tissue Sarcoma Using DOXOrubicin and Dacarbazine

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
SAAVI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests and management of hematuria updated; aprepitant added to Premedications; mesna dilution volume updated</i>	Therapy for Advanced Soft Tissue Sarcoma Using Ifosfamide
SAAVIME3	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests and management of hematuria updated; aprepitant added to Premedications</i>	3-Day Etoposide and Ifosfamide-Mesna for Patients with Advanced Soft Tissue or Bony Sarcomas (Inpatient)
SAIME	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol: Title and protocol simplified; Eligibility, Tests, Premedications, Dose Modifications updated; PPPO: cross referenced to other sarcoma protocols, urine dipstick added to Tests, Premedications updated</i>	Etoposide, Ifosfamide-Mesna (SAIME) for Use in Sarcomas
SAVAC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Title, Eligibility, Treatment and Dose Modification simplified; urine dipstick added to Tests</i>	Treatment of Sarcomas with vinCRiStine, DOXOrubicin and Cyclophosphamide (SAVAC)
SAVACM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Title, Eligibility, Treatment and Dose Modification simplified; Tests and management of hematuria updated</i>	Treatment of Sarcomas with Pelvic Primaries or Chemotherapy Induced Hematuria Using vinCRiStine, DOXOrubicin, Cyclophosphamide and Mesna
SAVDC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide infusion duration clarified</i>	Adjuvant Therapy for Rhabdomyosarcoma using vinCRiStine, Dactinomycin, and Cyclophosphamide
SAVDCM	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol simplified; urine dipstick added to Tests</i>	Adjuvant Therapy for Rhabdomyosarcoma using vinCRiStine, Dactinomycin, Cyclophosphamide and Mesna
SCMESNA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Mesna dosing simplified</i>	MESNA dosage modification for hematuria secondary to oxazaphosphorines (eg. Ifosfamide and Cyclophosphamide)
USMAVIPI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility updated</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/health-professionals/professional-resources/systemic-therapy/systemic-therapy-update
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
Cancer Drug Manual	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual
Cancer Management Guidelines	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-management-guidelines
Cancer Chemotherapy Protocols, Pre-Printed Orders, Protocol Patient Handouts	www.bccancer.bc.ca/health-professionals/professional-resources/chemotherapy-protocols
Systemic Therapy Program Policies	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
CON Pharmacy Educators	www.bccancer.bc.ca/health-professionals/professional-resources/pharmacy

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To update contact information of any CON sites, please contact:			
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	604-877-6000 x 672247		mclin@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		
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