Editor’s Choice

New Programs
Methotrexate for Low-Risk Gestational Trophoblastic Cancer (GOTDLRM) | Fedratinib for Symptomatic Myelofibrosis (ULKMFFED) | Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone for Previously Untreated Light Chain Amyloidosis (LYDARCBDF) | Revised Programs

Drug Update
Subcutaneous Daratumumab

Medication Safety
World Patient Safety Day

Provincial Systemic Therapy
Revised Policies III-60 Appendix: Drug Reaction Management – Physician Coverage During Delivery of Systemic Therapy | III-190: Oncology Biosimilars Utilization

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Scalp Cooling Systems

Cancer Drug Manual
Revised Abemaciclib, Atezolizumab, Avelumab, Brigatinib, Cemiplimab, Cytarabine, Daratumumab, Durvalumab, Encorafenib, Entrectinib, Fedratinib, Gemcitabine, Methotrexate, Mogamulizumab, Paclitaxel, Pembrolizumab, Ribociclib, Tislelizumab, Vinorelbine, IV Bag Size Selection Table

BC Cancer Benefit Drug List
New GOTDLRM, ULKMFFED, LYDARCBDF, Daratumumab subcutaneous injection | Revised UMYDARBD, MYDARCBDF, UMYDARLD, MYDARLDF

New Protocols, PPPOs and Patient Handouts
GO GOTDLRM | LK ULKMFFED | LY LYDARCBDF | MY UMYDARBD, MYDARCBDF, UMYDARLD, MYDARLDF

Revised Protocols, PPPOs and Patient Handouts
BR BRAVPBFLV, BRAVPTRAD, BRAVPTRAT, BRAVRBFLV | GU GUAVIPNI, GUAVPG | LY LYTCCOXMR | MY UMYDARBD, MYDARCBDF, UMYDARLD, MYDARLDF | SC SCNAUSEA | SM SMAJDT, SMAVDT

Resources and Contact Information

Editor’s Choice

New Programs

BC Cancer Provincial Systemic Therapy has approved the following new treatment programs effective 01 September 2022. Full details of all treatment programs are available in the Chemotherapy Protocols section of the BC Cancer website.

Gynecologic Oncology

Methotrexate for Low-Risk Gestational Trophoblastic Cancer (GOTDLRM) — The BC Cancer Genitourinary Tumour Group is implementing single-agent methotrexate for patients with low-risk gestational trophoblastic neoplasm (GTN) with a good initial response to first-line dactinomycin (GOTDLRA) but with gradual, indolent resistance based on hCG levels. Patients with poor initial response to first-line dactinomycin or with rapid resistance, in contrast, should be treated with GOTDEMACO. In GOTDLRM, methotrexate is administered by intramuscular (IM) injection on days 1, 3, 5 and 7, with oral leucovorin taken 30 hours after each methotrexate dose.

Until now, patients in BC who develop resistance to first-line dactinomycin are switched to combination dactinomycin and methotrexate (GOTDMR). This combination is more toxic than single-agent...
methotrexate, and may not provide an improved disease response due to potential resistance to dactinomycin. The most recent NCCN guideline identified patients who would be most appropriate for a switch from first-line dactinomycin to single-agent methotrexate. Amongst the various methotrexate regimens used for GTN, the regimen in GOTDLRM is preferred, given its well-established efficacy.²

**Leukemia**

**Fedratinib for Symptomatic Myelofibrosis (ULKMFFED)** — The BC Cancer Leukemia and BMT Tumour Group is introducing fedratinib, an oral JAK2 and FLT3 inhibitor, for patients with symptomatic myelofibrosis (MF) (primary, post-essential thrombocythemia, or post-polycythemia vera MF).³ Myelofibrosis is a hematological malignancy characterized by progressive fibrosis of the bone marrow, leading to multi-organ extramedullary hematopoiesis that prominently involves the spleen. Patients with MF suffer from symptomatic splenomegaly, anemia, debilitating constitutional symptoms and shortened survival. The current standard of care for patients with splenomegaly or symptoms related to MF is ruxolitinib, a JAK 1/2 inhibitor (ULKMFRUX), however until now there were no treatment options for patients unable to take ruxolitinib; patients with intolerance or contraindication to ruxolitinib are eligible to receive fedratinib. Oral thiamine (vitamin B1) supplementation is necessary during fedratinib treatment to prevent thiamine deficiency-associated Wernicke’s encephalopathy. BC Cancer Compassionate Access Program (CAP) approval is required.

The randomized, placebo-controlled phase III JAKARTA trial evaluated fedratinib in patients with MF who had not received previous treatment with a JAK inhibitor.⁴ A significantly greater proportion of patients treated with fedratinib 400 mg achieved the primary end point of spleen response (≥35% reduction in spleen volume from baseline) (36.5% vs. 1%, between-group difference = 35.4%, 97.5% CI 24.2-46.7). Treatment with fedratinib was also associated with a statistically significant and clinically meaningful improvement in disease-related symptoms (proportion of patients who had a ≥50% reduction in the total symptom score from baseline) (39.6% vs. 8.2%, between-group difference = 31.3%, 95% CI 18.0-44.6). Common adverse events with fedratinib were anemia, gastrointestinal symptoms, and increased levels of liver transaminases, serum creatinine and pancreatic enzymes.

**Lymphoma**

**Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone for Previously Untreated Light Chain Amyloidosis (LYDARCBDF)** — The BC Cancer Lymphoma and Myeloma Tumour Group is introducing the first Health Canada-approved treatment for patients with light chain (AL) amyloidosis. AL amyloidosis is a symptomatic plasma cell dyscrasia that arises due to secretion of abnormal clonal light chains (amyloid proteins) that deposit in the tissues of vital organs, causing organs to malfunction and eventually fail. The degree to which the heart is involved has the most influence in determining long-term prognosis. Previously, the standard of care has consisted of therapies typically used for myeloma such as cyclophosphamide, bortezomib and dexamethasone (CyBorD), and there has been a need for AL amyloidosis-specific treatment that can prevent, delay or improve disease-related organ damage.⁵ In LYDARCBDF, subcutaneous daratumumab is used in combination with cyclophosphamide, bortezomib, and dexamethasone (DCyBorD). Patients with previously untreated disease involving at least one organ system, and who are ineligible for stem cell transplant, are eligible for this treatment protocol. Patients who are currently on a first-line therapy that started prior to 01 September 2022 may switch to LYDARCBDF if they have not experienced progression and meet other eligibility criteria. Note that for patients transitioning therapies, the protocol code designation may change from MY (reflecting a CAP-approved myeloma protocol) to LY (for the AL amyloidosis-specific LYDARCBDF protocol).
Editor’s Choice

New Programs

Supporting evidence for this treatment program comes from the ongoing, randomized, open-label, phase III ANDROMEDA trial comparing DCyBorD to CyBorD in patients with newly diagnosed AL amyloidosis. At a median follow-up of 11.4 months, there was a statistically significant and clinically meaningful improvement in hematologic complete response (CR) rate in the daratumumab group (53.3% vs. 18.1%, RRR 2.9, 95% CI 2.1-4.1). The improvement in hematologic CR rate was consistent across patient subgroups of any cardiac stage and those with and without a t(11;14) translocation. The results for other response end points, including time to hematologic response and organ response (cardiac and renal), also favoured treatment with DCyBorD. The most common grade 3 or 4 adverse events were more common in the daratumumab group: lymphopenia (13.0% vs. 10.1%), pneumonia (7.8% vs. 4.3%) and cardiac failure (6.2% vs. 4.8%). Systemic administration-related reactions with subcutaneous daratumumab occurred in 7.3% of patients.

References

Revised Programs

Skin and Melanoma

Treatment-Related Pyrexia with Dabrafenib and Trametinib

Treatment-related pyrexia is a common adverse effect seen with the combination of dabrafenib and trametinib. The dosing modification for trametinib in the management of pyrexia has been updated when it is used in combination with dabrafenib (SMAJDT, SMAVDT). Previously, only dabrafenib was held for pyrexia while trametinib could be continued. The new recommendation is to hold both agents for pyrexia. The Canadian guideline recommends this approach based on recent clinical trials.

Reference
Drug Update

Launch of Subcutaneous Daratumumab

Effective 01 September 2022, all treatment protocols with intravenous (IV) daratumumab have been revised to include the subcutaneous (subcut) daratumumab 1800 mg fixed dose option (UMYDARBD, MYDARCBDF, UMYDARLD, MYDARLDF). The new treatment protocol, LYDARCBD (see Editor’s Choice above), includes only subcutaneous daratumumab.

Patients starting on daratumumab treatments can receive subcutaneous daratumumab starting from the first dose. For patients who have already started their IV daratumumab treatments, they can receive their subsequent doses administered as subcutaneous injection (EXCEPTION: patients must receive both doses of 8 mg/kg on Cycle 1 Days 1 and 2 before switching to daratumumab subcutaneous 1800 mg). The prescribers will decide if a patient can be switched to subcutaneous daratumumab. For operational considerations, patients switching from IV to subcutaneous daratumumab should complete their current cycle before making the change, rather than changing routes of administration at mid-cycle.

<table>
<thead>
<tr>
<th>Treatments</th>
<th>Intravenous Daratumumab</th>
<th>Subcutaneous Daratumumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 1</td>
<td>16 mg/kg on Days 1, 8, 15, 22 Or 8 mg/kg on Days 1 and 2, then 16 mg/kg on Days 8, 15, 22</td>
<td>1800 mg subcut on Days 1, 8, 15, 22</td>
</tr>
<tr>
<td>Cycle 2</td>
<td>16 mg/kg on Days 1, 8, 15, 22</td>
<td>1800 mg subcut on Days 1, 8, 15, 22</td>
</tr>
<tr>
<td>Cycles 3 to 6</td>
<td>16 mg/kg on Days 1 and 15</td>
<td>1800 mg subcut on Days 1 and 15</td>
</tr>
<tr>
<td>Cycle 7 and subsequent cycles</td>
<td>16 mg/kg on Day 1</td>
<td>1800 mg subcut on Day 1</td>
</tr>
</tbody>
</table>

Advantages

Subcutaneous daratumumab is the preferred route of administration. It has a decreased incidence of administration-related systemic reactions compared to IV administration. Subcutaneous daratumumab has a shorter administration time, allowing for shorter chair time for the patients compared to IV daratumumab, starting with their very first dose. Less frequent monitoring of vitals is required with subcutaneous administration. In addition, an observation period is only required following the first subcutaneous dose (more details below). Subcutaneous daratumumab is given as a fixed dose and it is available in a ready-to-use, single dose vial, so there is no need for weight-based calculations and further dilution, resulting in reduced preparation time, drug wastage, and potential for dosing errors.

Dosing and Administration

The IV and subcutaneous formulations are NOT interchangeable. Subcutaneous daratumumab is administered as a single injection subcutaneously into the abdomen by a systemic therapy trained nurse over approximately 5 minutes. There are no data regarding the injection of subcutaneous daratumumab at sites other than the abdomen.

The subcutaneous formulation contains the enzyme hyaluronidase to temporarily degrade the extracellular matrix under the skin. This increases the permeability of subcutaneous tissue to allow the absorption of 15 mL of daratumumab. Hence, the 15 mL dose should not be divided into multiple syringes. If a complete dose of subcutaneous daratumumab cannot be completed at a single site due to intolerance, administer the remaining dose at a second injection site on the opposite side of the abdomen.
Launch of Subcutaneous Daratumumab

Hyaluronidase may increase the systemic absorption of other drugs administered near the injection site for 24-48 hours. Therefore, other subcutaneous drugs should be administered at other sites whenever possible, such as when subcutaneous bortezomib and subcutaneous daratumumab are administered on the same day. Topical creams used to manage injection site discomfort, such as hydrocortisone 1%, diphenhydramine 2%, and EMLA, are unlikely to result in significant systemic toxicity because the systemic drug levels are relatively low even if fully absorbed.

Reactions, Monitoring and Observation

Premedications (antihistamines, antipyretics, corticosteroids) are the same for both subcutaneous and IV daratumumab. Because it takes longer to administer IV daratumumab (Cycle 1, Day 1), repeating premedications is sometimes necessary during intravenous infusion of daratumumab.

Serious administration-related systemic reactions are less common with subcutaneous daratumumab compared to IV daratumumab (8 - 13% vs. 35 - 48%). These usually occur with the first dose and rarely after subsequent doses. Symptoms of administration-related systemic reactions for subcutaneous daratumumab are consistent with those reported for the IV formulation. Respiratory symptoms (e.g., cough, wheeze, larynx and throat irritation, nasal congestion), chills, nausea, and vomiting may occur. Severe reactions have also been reported, including bronchospasm, laryngeal and pulmonary edema, hypertension, hypoxia, and dyspnea. Injection site reactions such as erythema, induration, and pruritus may also occur with subcutaneous daratumumab in up to 8% of patients.

Nearly all reactions would occur shortly after the subcutaneous injection. Patients should be monitored for 1 hour after administration on Cycle 1 Day 1, with physician to be on site for this observation. Observation is not required for subsequent doses, except at physician discretion. Vital signs should be checked immediately prior to the injection, at the end of the injection, and as needed.

For patients switching from IV to subcutaneous route, patients should be observed for 30 minutes after the first subcutaneous injection. Vital signs should be checked immediately prior to the injection and at the end of the injection, and as needed.

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Intravenous Daratumumab</th>
<th>Subcutaneous Daratumumab</th>
</tr>
</thead>
</table>
| Vitals Signs* | Cycle 1 Day 1 (and Day 2 if using Alternative regimen):  
• Before the start of infusion  
• During infusion: every 30 minutes x 4, then every 1 to 2 hours until the end of infusion  
• 30 minutes after the end of infusion | Cycle 1 Day 1:  
• Immediately prior to injection  
• At the end of injection  
• At the end of observation period OR  
If switching from IV to subcut daratumumab:  
• Immediately prior to injection  
• At the end of injection |
| Subsequent infusions (i.e., Cycle 1 Day 8 and beyond):  
• Before start of infusion  
• At the end of infusion | Subsequent injections:  
• Only as needed |
| Observation Period | 30 minutes after the end of infusion for first 3 infusions | If no previous daratumumab:  
• 1 hour after administration on Cycle 1 Day 1  
If switching from IV to subcut daratumumab:  
• 30 minutes after administration of first subcut dose only |
Launch of Subcutaneous Daratumumab

Medication Safety Considerations

Contributing factors to look-alike/sound-alike (LASA) error risks include:

- Same generic name and very similar brand names
- Vial concentrations look similar (20 mg/mL vs. 120 mg/mL)
- Potential dosing overlap (e.g., IV: 16 mg/kg in 112.5 kg patient = 1800 mg; subcut = 1800 mg)
- Risk of wrong route of administration (15 mL is uncommon volume for subcutaneous injection)

Strategies to mitigate LASA error risks include:

- **Physical separation:** Store the two products in distinct bins and never gather products in batch or have both products in the same IV preparation hood at the same time. Handle one drug per patient in the hood at a given time.
- **Product differentiation:** Distinguish the two products for order entry and on the drug label; create visible alerts for product selection at storage site.
- **Product checking:** Incorporate independent double-checking at appropriate steps in the compounding process to facilitate catching LASA mix-up. Use technology such as barcode scanning where available.
- **Raise awareness:** Educate all staff involved in handling both products in the medication management process. Assess local processes to determine the best risk mitigation strategies for your site.

Product Comparison

<table>
<thead>
<tr>
<th>Products</th>
<th>Intravenous daratumumab</th>
<th>Subcutaneous daratumumab</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Image</strong></td>
<td><img src="image1" alt="Product Image" /></td>
<td><img src="image2" alt="Product Image" /></td>
</tr>
<tr>
<td><strong>Brand Name</strong></td>
<td>DARZALEX</td>
<td>DARZALEX SC</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Colourless to yellow solution</td>
<td>Colourless to yellow solution; contains hyaluronidase</td>
</tr>
<tr>
<td><strong>Vial Solution Concentration</strong></td>
<td>20 mg/mL</td>
<td>120 mg/mL</td>
</tr>
<tr>
<td><strong>Vial Solution Volume</strong></td>
<td>100 mg/5 mL</td>
<td>1800 mg/15 mL</td>
</tr>
<tr>
<td></td>
<td>400 mg/20 mL</td>
<td></td>
</tr>
<tr>
<td><strong>Vial Storage</strong></td>
<td>Refrigerator</td>
<td>Refrigerator</td>
</tr>
<tr>
<td><strong>Final Preparation</strong></td>
<td>IV bag</td>
<td>Syringe</td>
</tr>
<tr>
<td><strong>Administration Route</strong></td>
<td>IV infusion</td>
<td>Subcutaneous injection over 5 minutes</td>
</tr>
<tr>
<td><strong>Typical Dosing</strong></td>
<td>16 mg/kg</td>
<td>or 8 mg/kg split dosing on Cycle 1 Days 1 and 2</td>
</tr>
</tbody>
</table>
Medication errors and unsafe medication practices are leading causes for preventable harm in healthcare. Globally, the estimated cost associated with medication errors is $42 billion USD per year. The ongoing COVID-19 pandemic has significantly exacerbated the risk of medication errors and associated medication-related harm due to stresses placed on the healthcare system. Hence, the World Health Organization (WHO) has chosen Medication Safety as the theme for World Patient Safety Day 2022, with the slogan Medication Without Harm. The WHO call-to-action is Know. Check. Ask.

Medication safety is particularly important in oncology practice because of the complexity of cancer treatment protocols and the risks associated with drugs with narrow therapeutic indices. Important components of medication safety include: teamwork, communication, systems thinking (e.g., understanding workflow, how processes relate), human factors (e.g., understanding how people interact with equipment and work environment), learning from medication incidents and managing risks. A patient safety culture that supports a safe environment for staff to report and follow up on errors is also essential.

At BC Cancer, many strategies are in place to enhance medication safety, starting from prescribing and extending to preparation and administration. Interdisciplinary teamwork, in collaboration with patient partners, is a key component to strengthening the medication system. Patient safety learning system (PSLS) is used to report errors, with subsequent systematic reviews conducted to prevent future errors.

Ongoing improvement opportunities exist to ensure the safe delivery of cancer treatments. As World Patient Safety Day approaches, this article is the first of a series that will share medication safety pearls and strategies.

**Medication Safety Pearl #1:** The World Health Organization’s call-to-action: Know. Check. Ask.

**KNOW** your medication

**CHECK** you have the right

✓ Patient
✓ Medicine
✓ Route
✓ Dose
✓ Time
✓ Reason * this additional check done at BC Cancer
✓ Documentation * this additional check done at BC Cancer

**ASK** your patient if they understand

**References**

**Provincial Systemic Therapy**

All Systemic Therapy policies are on the Shared Health Organizations Portal (SHOP) BC Cancer page.

**Policy III-60 Appendix: Drug Reaction Management – Physician Coverage**

Subcutaneous daratumumab has been added to the Appendix to Systemic Therapy Policy III-60: Drug Reaction Management – Physician Coverage During Delivery of Selected Systemic Therapy Drugs.

**Policy III-190: Oncology Biosimilars Utilization**

The advanced breast cancer treatment protocols that use a combination of trastuzumab and pertuzumab (BRAVPTRAD, BRAVPTRAT) are no longer an exception to the biosimilars policy. Previously, the trastuzumab reference biologic, HERCEPTIN, was used for all patients receiving treatment with one of these protocols. Moving forward, only biosimilar trastuzumab will be funded for treatment starting on or after 01 September 2022. Systemic Therapy Policy III-190: Oncology Biosimilars Utilization is being updated.

**Patients’ Corner**

**Scalp Cooling Systems**

Scalp cooling is a strategy that may be used in the prevention of chemotherapy-induced alopecia. A new patient-led approach for cold caps is under development, with implementation anticipated 01 October 2022. The new Systemic Therapy Policy III-230: Cooling Systems and Cold Caps for Chemotherapy-Induced Alopecia will allow patients to bring a privately purchased cold cap to their chemotherapy treatments for personal use. An educational patient handout will be available in several languages in the Coping with Cancer > Managing Symptoms & Side Effects > Hair Loss & Appearance section of the BC Cancer website. Nurses and BC Cancer staff will not be providing support on these systems in any capacity. Please contact your local chemotherapy unit leadership for specific procedures and any questions. Policy III-230 will be available on the SHOP BC Cancer page.

**Cancer Drug Manual©**

All documents are available in the Cancer Drug Manual© on the BC Cancer website.

**Revised Documents**

**Abemaciclib Monograph**

*Caution*: added statement about dose adjustment for drug interactions
*Interactions*: added new recommendations for abemaciclib dose adjustment
*Dosing Guidelines*: added statement about dose adjustment for drug interactions
**Atezolizumab Monograph and Patient Handout**
*Cautions*: added statement about vaccine response
*Patient Handout*: added statement about vaccine response to bullets

**Avelumab Monograph, Patient Handout and Chemotherapy Preparation and Stability Chart**
*Cautions*: added statement about vaccine response
*Patient Handout*: added statement about vaccine response to bullets
*Chemotherapy Preparation and Stability Chart*: deleted recommendation to equilibrate vial to RT prior to use as not applicable to the marketed brand

**Brigatinib Monograph**
*Cautions*: added statement about dose adjustment for drug interactions
*Dosing Guidelines*: added statement about dose adjustment for drug interactions

**Cemiplimab Monograph and Patient Handout**
*Cautions*: added statement about vaccine response
*Patient Handout*: added statement about vaccine response to bullets

**Cytarabine Chemotherapy Preparation and Stability Chart**
*PMS brand*: added (deleted in error)

**Daratumumab Monograph, SC Patient Handout, IV Patient Handout and Chemotherapy Preparation and Stability Chart**
*Common Trade Name*: added brand name for subcutaneous (SC) injection
*Pharmacokinetics table*: updated for SC administration
*Uses*: updated Health Canada approved indications
*Contraindications*: added contraindications for hypersensitivity
*Cautions*: added statement about the non-interchangeability of IV and SC formulations
*Side Effects*: added injection site reactions and administration-related reactions to SE table; added new paragraph for administration-related reactions following SC injection
*Supply and Storage*: added new SC formulation
*Supply and Storage (Additional information)*: added information related to the SC formulation (description of hyaluronidase and storage of unpunctured vials)
*Solution Preparation and Compatibility (Additional information)*: updated IV formulation; added SC formulation
*Parenteral Administration table*: added information related to SC administration
*Dosage Guidelines*: updated IV dosing; added SC dosing; added new/updated BC Cancer protocols
*SC Patient Handout*: created new handout for SC administration
*IV Patient Handout*: updated header/footer, drug name, and bullets to differentiate from new SC handout
*Chemotherapy Preparation and Stability Chart*: added new SC formulation

**Durvalumab Monograph and Patient Handout**
*Cautions*: added statement about vaccine response
*Patient Handout*: added statement about vaccine response to bullets
Encorafenib Monograph
Caution: added statement about dose adjustment for drug interactions
Dosing Guidelines: added statement about dose adjustment for drug interactions

Entrectinib Monograph
Caution: added statement about dose adjustment for drug interactions
Dosing Guidelines: added statement about dose adjustment for drug interactions

Fedratinib Monograph
Caution: updated recommendation for thiamine supplementation in Wernicke’s encephalopathy bullet; added statement about dose adjustment for drug interactions
Side Effects: updated information related to thiamine deficiency in encephalopathy paragraph
Dosage Guidelines: bolded and italicized BC Cancer standard dosing for new protocol (ULKMFED)

Gemcitabine Chemotherapy Preparation and Stability Chart
Pfizer/Hospira brand: added information related to refrigerator storage
Sandoz brand: added information related to refrigerator storage

Methotrexate Monograph and Patient Handout
Uses: updated Health Canada approved indications
Special Precautions: updated carcinogenicity, mutagenicity, and fertility
Supply and Storage: updated with current Canadian brands
Parenteral Administration Table: updated intramuscular administration
Dosage Guidelines: updated intramuscular administration
Dosage Guidelines (renal impairment): added recommended IM dosing adjustment
Patient Handout (IV): added intramuscular route; changed route in title

Mogamulizumab Interim Monograph
Caution: added statement about vaccine response

Paclitaxel Chemotherapy Preparation and Stability Chart
Accord brand: updated final product stability

Pembrolizumab Monograph and Patient Handout
Caution: added statement about vaccine response
Patient Handout: added statement about vaccine response to bullets

Ribociclib Monograph
Caution: added statement about dose adjustment for drug interactions
Dosing Guidelines: added statement about dose adjustment for drug interactions

Tislelizumab Interim Monograph
Caution: added statement about vaccine response

Vinorelbine Chemotherapy Preparation and Stability Chart
Pfizer brand: deleted as no longer marketed
The following treatment programs have been added to the Benefit Drug List effective 01 September 2022:

<table>
<thead>
<tr>
<th>Protocol Title</th>
<th>Protocol Code</th>
<th>Benefit Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy for Low-Risk Gestational Trophoblastic Cancer using Methotrexate</td>
<td>GOTDLRM</td>
<td>Class I</td>
</tr>
<tr>
<td>Treatment of Symptomatic Myelofibrosis with Fedratinib</td>
<td>ULKMMFFED</td>
<td>Restricted</td>
</tr>
<tr>
<td>Treatment of Previously Untreated Light Chain Amyloidosis and Not-Eligible for Stem Cell Transplant using Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone</td>
<td>LYDARCDBDF</td>
<td>Class I</td>
</tr>
<tr>
<td>Daratumumab subcutaneous injection (DARZALEX SC) has been added to the BC Cancer Benefit Drug List</td>
<td><strong>See BC Cancer Benefit Drug List – Revised Programs, immediately below, for applicable protocols</strong></td>
<td></td>
</tr>
</tbody>
</table>

The following treatment programs have been revised on the Benefit Drug List effective 01 September 2022:

<table>
<thead>
<tr>
<th>Protocol Title</th>
<th>Protocol Code</th>
<th>Benefit Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone with or without Cyclophosphamide ✓ Daratumumab subcutaneous injection added to protocol</td>
<td>UMYDARBD</td>
<td>Restricted</td>
</tr>
<tr>
<td>Treatment of Previously Untreated Multiple Myeloma and Not-Eligible for Stem Cell Transplant using Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone ✓ Daratumumab subcutaneous injection added to protocol</td>
<td>MYDARCDBDF</td>
<td>Class I (previously Restricted)</td>
</tr>
<tr>
<td>Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Lenalidomide and Dexamethasone ✓ Daratumumab subcutaneous injection added to protocol</td>
<td>UMYDARLD</td>
<td>Restricted</td>
</tr>
<tr>
<td>Treatment of Previously Untreated Multiple Myeloma and Not-Eligible for Stem Cell Transplant using Daratumumab, Lenalidomide and Dexamethasone ✓ Daratumumab subcutaneous injection added to protocol</td>
<td>MYDARLDF</td>
<td>Class I (previously Restricted)</td>
</tr>
</tbody>
</table>
**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 ✓)*

<table>
<thead>
<tr>
<th>Protocol Code</th>
<th>Protocol Title</th>
<th>Protocol</th>
<th>PPPO</th>
<th>Handout</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOTDLRM</td>
<td>Therapy for Low-Risk Gestational Trophoblastic Cancer using Methotrexate</td>
<td>✓</td>
<td>✓</td>
<td>❑</td>
</tr>
<tr>
<td>ULKMFFED</td>
<td>Treatment of Symptomatic Myelofibrosis with Fedratinib</td>
<td>✓</td>
<td>✓</td>
<td>❑</td>
</tr>
<tr>
<td>LYDARCBDF</td>
<td>Treatment of Previously Untreated Light Chain Amyloidosis and Not-Eligible for Stem Cell Transplant using Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone</td>
<td>✓</td>
<td>✓</td>
<td>❑</td>
</tr>
<tr>
<td>UMYDARBD</td>
<td>Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone with or without Cyclophosphamide</td>
<td>❑</td>
<td>✓</td>
<td>❑</td>
</tr>
<tr>
<td>MYDARCBDF</td>
<td>Treatment of Previously Untreated Multiple Myeloma and Not-Eligible for Stem Cell Transplant using Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone</td>
<td>❑</td>
<td>✓</td>
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<td>UMYDARLD</td>
<td>Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Lenalidomide and Dexamethasone</td>
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### REVISED Protocols, PPPOs and Patient Handouts *(revisions in respective columns)*

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<tr>
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<th>PPPO</th>
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<tr>
<td>BR</td>
<td>Breast</td>
<td></td>
<td>••</td>
<td>Mitte clarified</td>
</tr>
<tr>
<td>BRAVPBFLV</td>
<td>Therapy of Advanced Breast Cancer using Palbociclib and Fulvestrant with or without LHRH Agonist</td>
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**GU | Genitourinary**

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<thead>
<tr>
<th>GUAVIPNI</th>
<th>Treatment of Metastatic or Advanced Renal Cell Carcinoma using Ipilimumab and Nivolumab</th>
<th>Ipilimumab infusion time revised</th>
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<tr>
<td>GUAVPG</td>
<td>Palliative Therapy for Urothelial Carcinoma using Cisplatin and Gemcitabine</td>
<td>Tests updated</td>
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</tbody>
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**LY | Lymphoma**

| LYCODOXMRI      | Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab | -----                                                                                                     | Hypersensitivity banner added                                                    | -----                  |

**MY | Myeloma**

<p>| UMYDARBD        | Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone with or without Cyclophosphamide | Premedications, Treatment, Dose Modifications and Precautions updated; subcutaneous daratumumab added | Premedications clarified; bortezomib dosing and subcutaneous daratumumab options added PPPOs: IV Cycle 1 IV Cycle 2+ subcut (new) | Subcutaneous daratumumab added |</p>
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**SC | Supportive Care**

| SCNAUSEA | Prevention and Treatment of Chemotherapy-Induced Nausea and Vomiting in Adults | Hyperlink updated | ----- |

**SM | Skin and Melanoma**

| SMAJDT | Adjuvant Treatment of Stage III and IV, BRAF-Mutated, Fully Resected Melanoma using Dabrafenib and Trametinib | Dose Modifications and Precautions updated (pyrexia) | ----- | Side effects updated |
| SMAVDT | Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma using Dabrafenib and Trametinib | Dose Modifications and Precautions updated (pyrexia) | ----- | Side effects updated |
Resources and Contact Information

<table>
<thead>
<tr>
<th>Resource</th>
<th>Phone</th>
<th>Email / Toll Free / Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic Therapy Update: <a href="http://www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/systemic-therapy-update">www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/systemic-therapy-update</a></td>
<td></td>
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<tr>
<td>Systemic Therapy Update Editor</td>
<td>604-877-6000 x 672649</td>
<td><a href="mailto:bulletin@bccancer.bc.ca">bulletin@bccancer.bc.ca</a></td>
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<tr>
<td>Oncology Drug Information Cancer Drug Manual Editor</td>
<td>604-877-6275</td>
<td><a href="mailto:druginfo@bccancer.bc.ca">druginfo@bccancer.bc.ca</a></td>
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<tr>
<td>Pharmacy Oncology Certification Nurse Educators</td>
<td>250-519-5500 x 693742</td>
<td><a href="mailto:nbadry@bccancer.bc.ca">nbadry@bccancer.bc.ca</a></td>
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<tr>
<td></td>
<td>250-712-3900 x 686820</td>
<td><a href="mailto:rxchemocert@bccancer.bc.ca">rxchemocert@bccancer.bc.ca</a></td>
</tr>
<tr>
<td></td>
<td>604-877-6000 x 672638</td>
<td><a href="mailto:nursinged@bccancer.bc.ca">nursinged@bccancer.bc.ca</a></td>
</tr>
<tr>
<td>CAP – Compassionate Access Program</td>
<td>604-877-6277</td>
<td><a href="mailto:cap_bcca@bccancer.bc.ca">cap_bcca@bccancer.bc.ca</a> fax 604-708-2026</td>
</tr>
<tr>
<td>OSCAR – Online System for Cancer Drugs Adjudication and Reimbursement</td>
<td>888-355-0355</td>
<td><a href="mailto:oscar@bccancer.bc.ca">oscar@bccancer.bc.ca</a> fax 604-708-2051</td>
</tr>
<tr>
<td>Manufacturer Patient Assistance Programs: <a href="http://www.bccancer.bc.ca/mpap">http://www.bccancer.bc.ca/mpap</a></td>
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</tr>
<tr>
<td>Library/Cancer Information</td>
<td>604-675-8003</td>
<td><a href="mailto:requests@bccancer.bc.ca">requests@bccancer.bc.ca</a> toll free 888-675-8001 x 8003</td>
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<tr>
<td>Library Document Delivery</td>
<td>604-675-8002</td>
<td><a href="mailto:requests@bccancer.bc.ca">requests@bccancer.bc.ca</a></td>
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<td>Pharmacy Professional Practice Professional Practice, Nursing Provincial Systemic Therapy</td>
<td>604-877-6000 x 672247</td>
<td><a href="mailto:mlin@bccancer.bc.ca">mlin@bccancer.bc.ca</a></td>
</tr>
<tr>
<td></td>
<td>604-877-6000 x 672263</td>
<td><a href="mailto:BCancerPPNAdmin@ehnet.phsa.ca">BCancerPPNAdmin@ehnet.phsa.ca</a></td>
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<tr>
<td>BC Cancer – Abbotsford</td>
<td>604-851-4710</td>
<td>toll free 877-547-3777</td>
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<tr>
<td>BC Cancer – Kelowna</td>
<td>250-712-3900</td>
<td>toll free 888-563-7773</td>
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<td>250-645-7300</td>
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<td>604-930-2098</td>
<td>toll free 800-523-2885</td>
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<td>BC Cancer – Victoria</td>
<td>250-519-5500</td>
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Community Oncology Network (CON) sites: To update your contact information, please contact: bulletin@bccancer.bc.ca

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