



Provincial Health Services Authority

For the Patient: HNAJPMBPRT

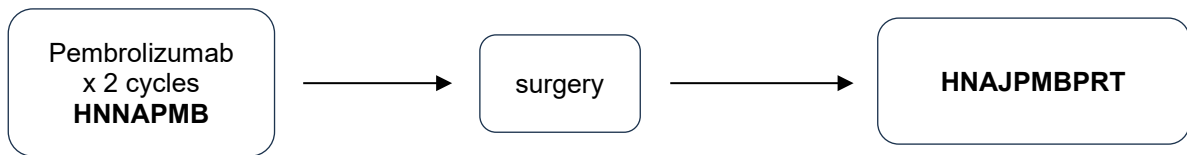
Other Names: Adjuvant Treatment of Squamous Cell Carcinoma of the Head and Neck using Pembrolizumab and Concurrent Cisplatin and Radiation

HN Head and Neck
AJ AdJuvant
PMB PeMBrolizumab
P cisPlatin
RT Radiation Therapy

ABOUT THIS TREATMENT

What these drugs are used for:

- HNAJPMBPRT is a drug and radiation treatment for squamous cell cancer of the head and neck.
- This treatment may reduce the chance of your cancer coming back.
- It is given after (called adjuvant) other types of treatment, such as surgery, and begins at the same time as the radiation therapy.
- It is given as the last step of a 3-step treatment:
 - First step: pembrolizumab before surgery
 - Second step: surgery
 - Third step: HNAJPMBPRT



How these drugs and radiation work:

- Pembrolizumab (pem" broe liz' ue mab) is a type of therapy called immunotherapy. It is an antibody designed to help your own body's immune system target cancer cells to stop them from growing.
- Cisplatin (sis-plat-in) is a platinum based anticancer drug that works by interfering with the genetic material of replicating cells and preventing an increase in the number of cancer cells.
- Radiation kills cancer cells and stops them from growing. When cisplatin is given with radiation, the cancer cells become more sensitive to radiation, and the treatment is more effective.

TREATMENT SUMMARY

Your treatment plan consists of two parts:

1. Radiation therapy and two drugs (initial 2 to 3 'cycles')
 - Each cycle lasts 3 weeks (21 days)
 - Some patients are admitted to hospital for the first three cycles, while others will be treated at the regional cancer center (called outpatient treatment). Your healthcare provider will decide which option is best for you.
 - Cycle 4 and onwards will be administered at the regional cancer centre.
 - Radiation is given daily Monday to Friday, with weekends and holidays off.
 - Pembrolizumab is given intravenously (through the vein) on Day 1 of each cycle. The infusion lasts about 30 minutes.
 - Cisplatin is given intravenously (through the vein) on Day 1 of Cycles 1 and 2. Your doctor will decide whether you will receive one more cisplatin dose on Day 1 of Cycle 3. The infusion lasts about 2 hours.
 - You will be given extra fluid intravenously before and after cisplatin. Hydration may last longer if you are receiving your treatment in the hospital.
2. After the radiation therapy portion is complete, you will continue to receive only pembrolizumab, once every 3 or 6 weeks. Pembrolizumab treatment will continue up to a maximum of 1 year (counted from the start of your pembrolizumab treatment given prior to surgery).

The calendar below outlines your overall treatment plan:

Cycles 1 and 2:

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---------------|---|-----------|-----------|-----------|-----------|-------|-------|
| Week 1 | Pembrolizumab Cisplatin Radiation | Radiation | Radiation | Radiation | Radiation | | |
| Week 2 | Radiation | Radiation | Radiation | Radiation | Radiation | | |
| Week 3 | Radiation | Radiation | Radiation | Radiation | Radiation | | |

Cycle 3:

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 |
|---------------|---|------------------|------------------|------------------|------------------|-------|-------|
| Week 1 | Pembrolizumab | | | | | | |
| | <i>Only if determined by your treatment provider:</i> | | | | | | |
| | <i>Cisplatin Radiation</i> | <i>Radiation</i> | <i>Radiation</i> | <i>Radiation</i> | <i>Radiation</i> | | |
| Week 2 | No treatment | | | | | | |
| Week 3 | No treatment | | | | | | |

Cycle 4 and onward: you will receive pembrolizumab alone every 3 weeks **or** every 6 weeks (frequency determined with your healthcare provider).

ADDITIONAL MEDICATIONS

- You may be given a prescription for anti-nausea medications (to be filled at your regular pharmacy). Please bring your anti-nausea medications with you for each treatment. Your nurse will tell you when to take the anti-nausea medication.
- You may also need to take anti-nausea drugs at home after treatment. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.
- Check with your doctor or pharmacist before you start taking any new drugs including all prescription and nonprescription medicines, vitamins, and herbal supplements.

LAB REQUIREMENTS

- You will need a blood test prior to each treatment. Your healthcare team will review the results of the blood test. The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- **Unexpected and unlikely side effects can occur with any drug treatment. It is very important to report side effects to your doctor.**
- **Do not try to treat or diagnose symptoms yourself.** Getting medical treatment right away may keep the problem from becoming more serious.
- **Be aware that symptoms may be delayed and can develop months after your last dose.**
- **Tell** your doctor, dentist, and other health professionals that you are being treated with this treatment regimen before you receive any treatment from them. You should carry the BC Cancer **wallet card** for checkpoint inhibitor to alert health providers.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.
- This treatment may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with these medications and for 4 months after your treatment has ended. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.
- Cisplatin may cause sterility in men and menopause in women. If you plan to have children, discuss this with your doctor before being treated with cisplatin.
- **Do not receive any immunizations before discussing with your healthcare team.**
- Radiation can only cause side effects in the part of the body where it is delivered.
- Smoking is not advisable because it can make your side effects worse and can make the treatment less effective. Ask your healthcare team for more information; or visit www.quitnow.ca.

- **Pembrolizumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.** The following side effects were most frequently reported:
 - Diarrhea
 - itching, rash
 - joint pain
 - feeling tired
 - feeling less hungry
 - cough

The pembrolizumab side effects listed in the following tables are most likely to begin during treatment; however, side effects can show up months after your last pembrolizumab treatment. Tell your healthcare team as soon as possible if you have any of serious side effects listed in the table below or your symptoms get worse.

Serious Side Effects Associated with Pembrolizumab

| SERIOUS SIDE EFFECTS | How common is it? |
|---|---|
| <p>Inflammation of the intestines (colitis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself. • blood or mucus in stools or dark, tarry, sticky stools • severe stomach pain (abdominal pain) or tenderness | <p>Common (less than 1 in 10 but more than 1 in 100)</p> |
| <p>Inflammation of the thyroid gland (hyperthyroidism, hypothyroidism) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rapid heart beat • weight loss or gain • increased sweating • hair loss • feeling cold • constipation or diarrhea • your voice gets deeper • muscle aches • changes in sleep patterns | <p>Common (less than 1 in 10 but more than 1 in 100)</p> |
| <p>Inflammation of the pituitary gland (hypophysitis, hypopituitarism, including secondary adrenal insufficiency) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • weight loss • increased sweating, hot flashes • hair loss (includes facial and pubic) • feeling cold • headaches that will not go away or unusual headache • decreased sex drive • vision problems • excessive thirst and urination | <p>Common (less than 1 in 10 but more than 1 in 100)</p> |
| <p>Inflammation of the lungs (pneumonitis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • shortness of breath • chest pain • coughing | <p>Common (less than 1 in 10 but more than 1 in 100)</p> |
| <p>Problems with muscles <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • back pain • spasms • weakness • muscle pain | <p>Common (less than 1 in 10 but more than 1 in 100)</p> |
| <p>Skin problems <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rash | <p>Common (less than 1 in 10 but</p> |

| | |
|--|---|
| <ul style="list-style-type: none"> dry skin | more than 1 in 100) |
| Problems in other organs (nervous system, eyes) <i>Symptoms may include:</i> <ul style="list-style-type: none"> tingling, numbness, lack of energy changes in eyesight dizziness | <p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p> |
| Inflammation of the liver (hepatitis) <i>Symptoms may include:</i> <ul style="list-style-type: none"> nausea or vomiting loss of appetite pain on the right side of your stomach yellowing of your skin or the whites of your eyes dark urine bleeding or bruise more easily than normal | <p>Uncommon</p> <p>(less than 1 in 100 but more than 1 in 1000)</p> |
| Inflammation of the kidneys (nephritis) <i>Symptoms may include:</i> <ul style="list-style-type: none"> changes in the amount or colour of your urine | <p>Uncommon</p> <p>(less than 1 in 100 but more than 1 in 1000)</p> |
| Problems in the pancreas <i>Symptoms may include:</i> <ul style="list-style-type: none"> abdominal pain nausea and vomiting | <p>Rare</p> <p>(less than 1 in 1000 but more than 1 in 10000)</p> |
| Blood sugar problems (type 1 diabetes mellitus) <i>Symptoms may include:</i> <ul style="list-style-type: none"> hunger or thirst a need to urinate more often weight loss | <p>Rare</p> <p>(less than 1 in 1000 but more than 1 in 10000)</p> |
| Infusion reactions <i>Symptoms may include:</i> <ul style="list-style-type: none"> shortness of breath itching or rash dizziness fever wheezing flushing feeling like passing out | <p>Rare</p> <p>(less than 1 in 1000 but more than 1 in 10000)</p> |

Management of Other Side Effects

| OTHER SIDE EFFECTS | MANAGEMENT |
|--|---|
| Allergic reactions may rarely occur. Signs of an allergic reaction may include flushing, rash, itching, dizziness, swelling or breathing problems. This can occur immediately or several hours after receiving treatment. | Tell your nurse if this happens while you are receiving treatment or contact your oncologist immediately if this happens after you leave the clinic. |
| Cisplatin burns if it leaks under the skin. | Tell your nurse or doctor immediately if you feel burning, stinging, or any other change while the drug is being given. |

| OTHER SIDE EFFECTS | MANAGEMENT |
|---|--|
| Pain or tenderness may occur where the needle was placed. | Apply cool compresses or soak in cool water for 15 to 20 minutes several times a day. |
| Your white blood cells will decrease after your treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection. | To help prevent infection: <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Take care of your skin and mouth by gently washing regularly. • Avoid crowds and people who are sick. Call your healthcare team immediately at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough or burning when you pass urine. |
| Your platelets may decrease during or after your treatment. They will return to normal after your last treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual. | To help prevent bleeding problems: <ul style="list-style-type: none"> • Try not to bruise, cut or burn yourself. • Clean your nose by blowing gently, do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding. <i>Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart).</i> |
| Sore mouth may occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth or in the throat. Mouth sores or bleeding gums can lead to an infection. | <ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Avoid commercial mouthwashes because they have a high alcohol content and can dry and irritate the oral tissues. • Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day. • Try the ideas in <i>Food Ideas to Try with a Sore Mouth</i>.* |
| Nausea and vomiting may occur after your treatment and may last for 24 hours. Nausea may last longer for some patients (i.e., delayed nausea and vomiting). If you are vomiting and it is not controlled, you can quickly become dehydrated. | You will be given a prescription for anti-nausea drug(s) to take before your chemotherapy treatment and/or at home. It is easier to prevent nausea than to treat it once it has happened, so follow directions closely. <ul style="list-style-type: none"> • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.* |
| Changes in hearing may occur | Contact your healthcare team if you have any concerns in your hearing. |
| Numbness or tingling of the fingers or toes may sometimes occur. This will slowly return to normal once your treatments are | <ul style="list-style-type: none"> • Be careful when handling items that are sharp, hot or cold. |

| OTHER SIDE EFFECTS | MANAGEMENT |
|---|---|
| over. This may take several months. | <ul style="list-style-type: none"> • Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady. Tell your healthcare team at your next visit, especially if you have trouble with buttons, writing or picking up small objects, walking or have fallen. |
| Tiredness and lack of energy may sometimes occur. | <ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i>.* |
| Headache may sometimes occur. | <ul style="list-style-type: none"> • If headache is persistent and you have other symptoms of inflammation of glands, tell your healthcare team as soon as possible. (see the table above for serious side effects.) |
| Swelling of hands, feet or lower legs may occur if your body retains extra fluid | See or call your healthcare team as soon as possible. |
| Skin rashes may sometimes occur. | |
| Sugar control may commonly be affected in patients with diabetes. | |
| Loss of appetite and weight loss sometimes occur. | |
| You may sometimes have trouble sleeping . | Talk to your healthcare team if you continue to have trouble sleeping. This will return to normal when you stop treatment. |
| Increase in cholesterol or triglycerides (one of the types of fat in the blood) may sometimes occur. | Tell your doctor if you have: <ul style="list-style-type: none"> • A history of heart disease. • High blood pressure. • High cholesterol or triglycerides. You may need to have your cholesterol level checked a few months after starting pembrolizumab. |
| Hair loss is rare with cisplatin and pembrolizumab. Your hair will grow back once your treatment stops. Colour and texture may change. | If hair loss is a problem, refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout</i> .* |

*Please ask your nurse or pharmacist for a copy.

Management of Radiation Side Effects

| RADIATION SIDE EFFECTS | MANAGEMENT |
|---|--|
| <p>Skin irritation may occur while receiving radiation therapy, since all radiation must pass through your skin. The side effects will vary depending on amount of radiation given, the area of the body treated, the size of the treatment area, and whether chemotherapy has been previously administered. Skin may feel warm and sensitive and colour may change.</p> | <ul style="list-style-type: none"> • Bathe using lukewarm water and mild, unscented soap. Pat skin dry with a soft towel. • Wear loose, comfortable clothing. • Protect skin from direct sunlight and wind. Avoid extremes of hot or cold (heating pads, icepacks, hot tubs, saunas, etc.). • You may swim if skin is intact. • Avoid perfume, alcohol, astringents and adhesives to the treated areas during treatment. • Be careful not to remove the skin markings placed by the Radiation Therapists. • The Radiation Therapists will give you information about skin care. • If your skin begins to peel or blister, call the nursing line. |
| <p>Fatigue is a common side effect. This may last for several weeks after treatment.</p> | <ul style="list-style-type: none"> • Balancing rest, good nutrition, and fluid intake can help you manage this best. |
| <p>Loss of Taste may occur.</p> | <ul style="list-style-type: none"> • Tumours involving the 5th, 7th, 9th and 10th cranial nerves, radiation to the head and neck areas, and chemotherapy can all contribute to loss of taste sensation. • Refer to <i>Food Ideas to Cope with Taste and Smell Changes</i>.* |
| <p>Dry Mouth (xerostomia) may occur. If your salivary glands were in the treated area, you may develop a dry mouth. This dryness may be permanent. A dry mouth can lead to oral problems, so consult your dental team to help you manage these problems.</p> | <ul style="list-style-type: none"> • A decrease in salivary flow can lead to long term problem with dry mouth. A clean, well-hydrated mouth may prevent complications from cancer treatment. • You may need to moisten your mouth often, especially when eating and talking. • To aid in swallowing, foods may be softened with liquids such as skim milk, broth, or water. Foods with some bulk may be easier to swallow than liquids. • Avoid alcohol and caffeinated beverages which may cause dryness. Avoid carbonated beverages with sugar. Avoid diet drinks with phosphoric and citric acids. |
| <p>Swallowing Problems may occur. If you develop scar tissue in the throat, this may cause difficulty with swallowing.</p> | <ul style="list-style-type: none"> • Stretching exercises may help with this problem. • Consult a speech pathologist for assessment and advice. |

***Please ask your nurse or pharmacist for a copy**

CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.

- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin.
- Signs of an **allergic reaction** soon after a treatment including dizziness, fast heart beat, face and tongue swelling or breathing problems.
- **Diarrhea** or changes in **bowel habits**; black, tarry stools; blood or mucous in the stool; severe **abdominal pain**.
- Signs of **lung problems** such as new or worsening cough, chest pain, coughing blood, shortness of breath, or difficulty in breathing.
- Signs of **kidney problems** such as lower back or side pain, blood in the urine, swelling of feet or lower legs, or change in amount or colour of urine.
- Signs of **blood sugar problems** such as thirst and frequent need to pass urine.
- Signs of a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain or shortness of breath.
- Signs of **heart problems** such as fast or uneven heartbeat.
- **Seizures** or **loss of consciousness**.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Signs of **thyroid problems** such as unusual weight gain or loss, feeling hot or cold, deepened voice, or unusual tiredness or weakness.
- **Changes in eyesight, eye pain, or redness.**
- Ringing in your ears or **hearing problems**.
- **Skin rash, blisters, or itching.**
- **Stomach pain** not controlled by antacids or acetaminophen.
- Signs of **bladder problems** such as changes in urination, painful burning sensation, presence of blood or abdominal pain.
- Increased **sore throat or mouth** that makes it difficult to swallow comfortably.
- Uncontrolled nausea, vomiting or diarrhea

CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Changes in skin colour (lightening).
- Irritability or forgetfulness.
- Decreased sex drive.
- Redness, swelling, pain or sores where the needle was placed.
- Easy bruising or bleeding.
- Numbness or tingling in feet or hands or painful leg cramps.



Provincial Health Services Authority

MEDICAL ALERT

NAME _____

has received

CHECKPOINT INHIBITOR IMMUNOTHERAPY:

Immune-Mediated Adverse Reactions

ALWAYS CARRY THIS CARD AND SHOW TO PHYSICIANS INCLUDING ANESTHETISTS

SEVERE IMMUNE-MEDIATED ADVERSE REACTIONS

Including enterocolitis, intestinal perforation, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, endocrinopathy, pneumonitis, myositis, myocarditis and toxicities in other organ systems. Duration of risk after treatment is unknown.

FOR MORE INFORMATION:

- BC Cancer - Abbotsford604-851-4710
 - BC Cancer - Kelowna.....250-712-3900
 - BC Cancer - Prince George.....250-645-7300
 - BC Cancer - Surrey604-930-4055
 - BC Cancer - Vancouver.....604-877-6000
 - BC Cancer - Victoria.....250-519-5500
- www.bccancer.bc.ca/cdm

Rev Jul 2019

Name _____
PHN _____
Medical Oncologist _____
Treatment Drug _____

To Whom It May Concern:

This patient is receiving **immunotherapy** at the BC Cancer and is at risk of **immune-related toxicities** which may be life threatening and require urgent management.

Immunotherapy toxicities are different from those encountered with standard chemotherapy or targeted therapies. The immune system may become dysregulated during immunotherapy treatment, leading to symptoms and findings which mimic autoimmune disorders. Adverse events can occur during or following treatment and can be life threatening. Any organ system in the body is at risk including, but not limited to:

- Lungs (pneumonitis, pleuritis, sarcoidosis)
- Gastrointestinal (colitis, ileitis, pancreatitis)
- Liver (hepatitis)
- Skin (rash, Stevens-Johnson syndrome)
- Endocrine (hypophysitis, adrenal insufficiency, hypo/hyperthyroidism, type 1 diabetes mellitus)
- Renal (interstitial nephritis)
- Blood (hemolytic anemia, thrombocytopenia, neutropenia)
- Neurologic (encephalitis, Guillain-Barré syndrome, meningitis, myasthenia gravis, neuropathy)
- Musculoskeletal (myositis, arthritis)
- Cardiovascular (pericarditis, myocarditis, vasculitis)
- Ophthalmologic (uveitis, scleritis, episcleritis, conjunctivitis, retinitis)

Management of immune-related toxicities necessitates prompt coordination with a medical oncologist with **initiation of high dose corticosteroids**, and may require referral to the appropriate subspecialty. If you suspect your patient is presenting with immune-related toxicity, **please contact the patient's medical oncologist** directly or if after hours contact the on-call physician, or as per your local centre's process (next page). Additional information on immunotherapy toxicity treatment algorithms is located at the end of the above posted protocol at www.bccancer.bc.ca.

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| BC CANCER CENTRES | For PATIENTS: Provincial/Telephone Nurse Lines |
| Abbotsford Prince George Surrey Vancouver Victoria | Call the 24/7 Provincial Nurse Line (PNL): 1-833-818-ONCO(6626) |
| Kelowna | Between 8:30 am 4:30 pm Monday to Friday (excluding Statutory holidays) call: <ul style="list-style-type: none"> • Telephone Nurse Line call (250) 712-3944 or • 1-888-563-7773 ext. 683944 Outside these hours, call the Kelowna General Hospital switchboard at (250) 862-4000 and ask for the on-call medical oncologist. |

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|--------------------------|---|
| BC CANCER CENTRES | FOR HEALTHCARE PROVIDERS: <i>*To contact a patient's medical oncologist/hematologist directly by calling the centre's switchboard as listed below.</i> |
| Abbotsford | Call Abbotsford Regional Hospital and Cancer Centre switchboard at (604) 851-4700 and ask for the patient's oncologist/hematologist, or after hours, for Abbotsford on-call medical oncologist. |
| Kelowna | Call the Kelowna General Hospital switchboard at (250) 862-4000 and ask for the on-call medical oncologist. |
| Prince George | Call University Hospital of Northern British Columbia switchboard at (250) 565-2000 and ask for the on-call medical oncologist. |
| Surrey | Call the Surrey Memorial Hospital switchboard at (604) 581-2211 and ask for the Surrey on-call medical oncologist. |
| Vancouver | Call the BC Cancer Switchboard at (604) 877-6000 and press 1 and ask for the on-call medical oncologist. |
| Victoria | Call the Royal Jubilee Hospital switchboard at (250) 370-8000 and ask for the on-call medical oncologist. |