



Provincial Health Services Authority

For the Patient: HNAJPMB

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

HN Head and Neck

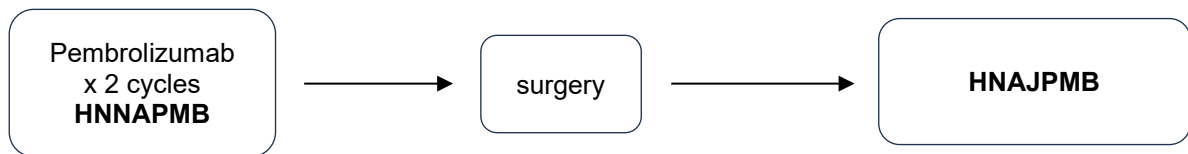
AJ AdJuvant

PMB PeMBrolizumab

ABOUT THIS TREATMENT

What this treatment is used for:

- HNAJPMB 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 is the last step of a 3-step treatment:
 - First step: pembrolizumab before surgery
 - Second step: surgery
 - Third step: HNAJPMB



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.
- Radiation kills cancer cells and stops them from growing.

TREATMENT SUMMARY

Your treatment plan consists of two parts:

1. Pembrolizumab with radiation therapy ('Cycles' 1 to 3)
 - Each cycle lasts 3 weeks (21 days)
 - 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.
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 to 3 (given every 3 weeks):

	Day 1	Day 2	Day 3	Day 4	Day 5
Cycle 1	Pembrolizumab Radiation*	Radiation	Radiation	Radiation	Radiation
Cycle 2	Pembrolizumab Radiation	Radiation	Radiation	Radiation	Radiation
Cycle 3	Pembrolizumab Radiation	Radiation	Radiation	Radiation	Radiation

*Radiation therapy typically lasts over six to six and a half weeks.

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 and for at least 4 months after the last dose.
- **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 style="text-align: center;">Common</p> <p style="text-align: center;">(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 style="text-align: center;">Common</p> <p style="text-align: center;">(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 style="text-align: center;">Common</p> <p style="text-align: center;">(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 • dry skin 	<p style="text-align: center;">Common</p> <p style="text-align: center;">(less than 1 in 10 but more than 1 in 100)</p>
<p>Problems in other organs (nervous system, eyes) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • tingling, numbness, lack of energy • changes in eyesight • dizziness 	<p style="text-align: center;">Common</p> <p style="text-align: center;">(less than 1 in 10 but more than 1 in 100)</p>
<p>Inflammation of the liver (hepatitis) <i>Symptoms may include:</i></p> <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 style="text-align: center;">Uncommon</p> <p style="text-align: center;">(less than 1 in 100 but more than 1 in 1000)</p>
<p>Inflammation of the kidneys (nephritis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • changes in the amount or colour of your urine 	<p style="text-align: center;">Uncommon</p> <p style="text-align: center;">(less than 1 in 100 but more than 1 in 1000)</p>
<p>Problems in the pancreas <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • abdominal pain • nausea and vomiting 	<p style="text-align: center;">Rare</p> <p style="text-align: center;">(less than 1 in 1000 but more than 1 in 10000)</p>

<p>Blood sugar problems (type 1 diabetes mellitus) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • hunger or thirst • a need to urinate more often • weight loss 	<p>Rare (less than 1 in 1000 but more than 1 in 10000)</p>
<p>Infusion reactions <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • shortness of breath • itching or rash • dizziness • fever • wheezing • flushing • feeling like passing out 	<p>Rare (less than 1 in 1000 but more than 1 in 10000)</p>

Management of Other Side Effects

OTHER SIDE EFFECTS	MANAGEMENT
<p>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.</p>	<p>Tell your nurse if this happens while you are receiving treatment or contact your oncologist immediately if this happens after you leave the clinic.</p>
<p>Pain or tenderness may occur where the needle was placed.</p>	<p>Apply cool compresses or soak in cool water for 15 to 20 minutes several times a day.</p>
<p>Your white blood cells may 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.</p>	<p>To help prevent infection:</p> <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. <p>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.</p>
<p>Headache, and/or muscle pain or joint pain may sometimes occur.</p>	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. • 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.).
<p>You may sometimes have trouble sleeping.</p>	<p>Talk to your healthcare team if you continue to have trouble sleeping. This will return to normal when you stop treatment.</p>
<p>Tiredness and lack of energy may sometimes occur.</p>	<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>*

OTHER SIDE EFFECTS	MANAGEMENT
<p>Nausea and vomiting may occur after your treatment. If you are vomiting and it is not controlled, you can quickly become dehydrated.</p>	<p>You may be given a prescription for anti-nausea drug(s) to take before your treatment and/or at home. It is easier to prevent nausea than to treat it once it has happened, so follow directions closely.</p> <ul style="list-style-type: none"> • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.*
<p>Swelling of hands, feet or lower legs may occur if your body retains extra fluid</p>	<p>See or call your healthcare team as soon as possible.</p>
<p>Skin rashes may sometimes occur.</p>	
<p>Sugar control may commonly be affected in patients with diabetes.</p>	
<p>Loss of appetite and weight loss sometimes occur.</p>	
<p>Diarrhea or constipation may sometimes occur.</p>	<p>Tell your doctor if you have:</p> <ul style="list-style-type: none"> • A history of heart disease. • High blood pressure. • High cholesterol or triglycerides. <p>You may need to have your cholesterol level checked a few months after starting pembrolizumab.</p>
<p>Hair loss does not occur with pembrolizumab.</p>	

*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.

RADIATION SIDE EFFECTS	MANAGEMENT
<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>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>Mouth Sores, commonly known as canker sores, may occur. These can become painful and may make it difficult to eat enough food.</p>	<ul style="list-style-type: none"> Early detection and treatment of oral infections will diminish the severity of mouth sores and pain associated with it. Avoid commercial mouthwashes because they have a high alcohol content and can dry and irritate the oral tissues. If you develop mouth or throat pain, please tell your oncologist. <p>Refer to <i>Dry Mouth and Mouth Pain from Cancer Treatments*</i></p>
<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. <p>Refer to <i>Food Ideas to Cope with Taste and Smell Changes.*</i></p>
<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 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.**
- Skin **rash, blisters**, or itching

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.



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.

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.

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.