For the Patient: BRAJPEM6

Other Names: Adjuvant Treatment of Resected Triple Negative Breast Cancer using Pembrolizumab

BR	**BR**east
AJ	**A**d**J**uvant
PEM	**Pem**brolizumab
6	**6**-weekly

ABOUT THIS TREATMENT

What is this treatment used for?

- BRAJPEM is a drug treatment given before and after breast cancer surgery (called neoadjuvant and adjuvant therapy), in the hope of destroying breast cancer cells that may have spread to other parts of your body.
- This treatment is for patients who have already completed treatment with a combination of pembrolizumab and chemotherapy, followed by surgery. It can also be used while you are waiting for surgery.

How does this treatment work?

- Pembrolizumab (pem'' broe liz' ue mab) is a monoclonal antibody, a type of protein designed to help your own body's immune system target cancer cells to stop them from growing. Pembrolizumab is a type of therapy called immunotherapy.

INTENDED BENEFITS

- This treatment may reduce the chance of your breast cancer coming back and may improve your overall survival or chance of a cure.

TREATMENT SUMMARY

How is this treatment given?

- Pembrolizumab will be given to you by injection into the vein (referred to as intravenously or IV) over approximately 10 minutes.
- You will be treated with pembrolizumab once every 6 weeks. This 6-week period is called a "cycle".
- You will receive approximately 1 year of pembrolizumab. This includes the cycles of pembrolizumab received before surgery.

The calendar below outlines your overall treatment plan for each cycle:

	DATE	TREATMENT PLAN
CYCLE		▶ Week 1 ➔ pembrolizumab on Day 1
		Week 2 ➔ no treatment
		Week 3 ➔ no treatment
		Week 4 ➔ no treatment
		Week 5 ➔ no treatment
		Week 6 ➔ no treatment

What will happen while I am being treated?

- You will have a blood test prior to each treatment. The dose and timing of your treatment may be changed based on the test results and/or other side effects.
- Your very first treatment will take longer than other treatments because a nurse will be reviewing the possible side effects of your chemotherapy plan and will discuss with you how to manage them. *It is a good idea to bring someone with you to your first chemotherapy appointment.*

INSTRUCTIONS FOR THE PATIENT

It is very important to report side effects immediately to your healthcare team. Do not manage side effects at home without speaking with your healthcare team. Be aware that symptoms may be delayed and can develop months after your last dose. If other healthcare professionals are involved in your care it is important they know you are on these treatments and the autoimmune side effects they can cause.

- **Before you are given pembrolizumab**, talk to your healthcare team if you:
  - have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn's disease, lupus, rheumatoid arthritis or sarcoidosis.
  - take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone or dexamethasone.
  - had an organ transplant, such as a kidney transplant.
  - have any other significant medical conditions.
- Other drugs may interact with pembrolizumab. Check with your healthcare team before you start or stop taking any other drugs including all prescription and non-prescription medicines, steroids or other medicines that lower your immune response, vitamins, and herbal supplements.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of pembrolizumab.
- Pembrolizumab may damage sperm and may harm the baby if used during pregnancy. You must use **birth control** while being treated with pembrolizumab and for at least 4 months after your last dose. Tell your healthcare team right away if you or your partner becomes pregnant. **Do not breastfeed** during treatment.

- ***Tell*** doctors, dentists and other health professionals that you are being treated with pembrolizumab before you receive any treatment from them. You should carry the BC Cancer ***wallet card*** for pembrolizumab to alert health providers.
- ***Do not receive any immunizations before discussing with your healthcare team***.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Pembrolizumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.

Are there any risks?
Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly relevant to your treatment plan.

What is the most important information I should know about SERIOUS SIDE EFFECTS?
- Pembrolizumab can cause serious side effects in many parts of your body. These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment with pembrolizumab.
- ***Tell*** your healthcare team as soon as possible if you have any of serious side effects listed in the table below or if your symptoms get worse.
- **Do not try to treat or diagnose symptoms yourself**. Getting medical treatment right away may keep the problem from becoming more serious.

The following side effects were most frequently reported:

Very common (more than 1 in 10 people)

• diarrhea
• itching, rash
• joint pain
• feeling tired
• feeling less hungry
• cough

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the intestines (colitis) *Symptoms may include:* • 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	Common (less than 1 in 10 but more than 1 in 100)

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the thyroid gland (hyperthyroidism, hypothyroidism) *Symptoms may include:* • 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	Common (less than 1 in 10 but more than 1 in 100)
Inflammation of the pituitary gland (hypophysitis, hypopituitarism, including secondary adrenal insufficiency) *Symptoms may include:* • tiredness • loss of appetite • 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	Common (less than 1 in 10 but more than 1 in 100)
Inflammation of the lungs (pneumonitis) *Symptoms may include:* • shortness of breath • chest pain • coughing	Common (less than 1 in 10 but more than 1 in 100)
Problems with muscles *Symptoms may include:* • back pain • spasms • weakness • muscle pain	Common (less than 1 in 10 but more than 1 in 100)
Skin problems *Symptoms may include:* • rash • dry skin	Common (less than 1 in 10 but more than 1 in 100)
Problems in other organs (nervous system, eyes) *Symptoms may include:* • tingling, numbness, lack of energy • changes in eyesight • dizziness	Common (less than 1 in 10 but more than 1 in 100)

SERIOUS SIDE EFFECTS	How common is it?
Blood sugar problems (type 1 diabetes mellitus) *Symptoms may include:* • hunger or thirst • a need to urinate more often • weight loss	Common (less than 1 in 10 but more than 1 in 100)
Inflammation of the liver (hepatitis) *Symptoms may include:* • 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	Uncommon (less than 1 in 100 but more than 1 in 1000)
Inflammation of the kidneys (nephritis) *Symptoms may include:* • changes in the amount or colour of your urine	Uncommon (less than 1 in 100 but more than 1 in 1000)
Problems in the pancreas *Symptoms may include:* • abdominal pain • nausea and vomiting	Rare (less than 1 in 1000 but more than 1 in 10000)
Infusion reactions *Symptoms may include:* • shivering, chills • shortness of breath • itching or rash • dizziness • fever • wheezing • flushing • feeling like passing out	Rare (less than 1 in 1000 but more than 1 in 10000)

OTHER SIDE EFFECTS	MANAGEMENT
Allergic reactions may rarely occur. Signs of an allergic reaction may include flushing, dizziness, swelling or breathing problems, fast or uneven heart beat, chest pain, rash, or itching. 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.

OTHER SIDE EFFECTS	MANAGEMENT
Pain or **tenderness** may occur where the needle was placed.	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Diarrhea may sometimes occur.	See your healthcare team or get emergency help.
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.	To help prevent infection: • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your healthcare team immediately at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, cough, or burning when you pass urine.
Fever may sometimes occur.	• Take acetaminophen (e.g., TYLENOL) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. • If you have other symptoms of **colitis**, tell your healthcare team as soon as possible. (see the table above for serious side effects.)
Constipation may sometimes occur.	• Exercise if you can. • Drink plenty of fluids. • Try ideas in *Food Choices to Manage Constipation.** • If you have other symptoms of **colitis**, tell your healthcare team as soon as possible. (see the table above for serious side effects.)
Headache, and/or muscle pain or joint pain may sometimes occur.	See or call your healthcare team as soon as possible.
Loss of appetite and **weight loss** sometimes occur.	
Nausea and **vomiting** may occur after your treatment. Most people have little or no nausea.	
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	
Sugar control may commonly be affected in patients with diabetes.	
Skin rashes may 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 pembrolizumab.
Increase in **cholesterol** or **triglycerides** (one of the types of fat in the blood) may sometimes occur.	Tell your healthcare team if you have: • 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.

OTHER SIDE EFFECTS	MANAGEMENT
Tiredness and lack of energy may sometimes occur.	• Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in *Fatigue/Tiredness- patient handout** • If tiredness is persistent and you have other symptoms of **hepatitis or inflammation of glands**, tell your doctor as soon as possible. (see the table above for serious side effects.)
Hair loss is rare with pembrolizumab.	If hair loss is a problem, refer to *Resources for Hair Loss and Appearance Changes – Patient Handout.**

*** Please ask a member of your healthcare team for a copy.**

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

- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heartbeat, face swelling or breathing problems.
- Signs of an **infection** such as fever (over 38ºC or 100ºF by an oral thermometer); chills, cough, pain or burning when you pass urine.
- **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 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.

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.

BC CANCER
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 - Abbotsford	604-851-4710
BC Cancer - Kelowna	250-712-3900
BC Cancer - Prince George	250-645-7300
BC Cancer - Surrey	604-930-4055
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: • 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:** ***To contact a patient's medical oncologist/hematologist directly by calling the centre's switchboard as listed below.***
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.