

For the Patient: LUSCATPE

Other Names: Treatment of Extensive Stage Small Cell Lung Cancer (SCLC) with Atezolizumab, Platinum and Etoposide

LU = LUng SC = Small Cell AT = ATezolizumab PE = CisPlatin, Etoposide

ABOUT THIS MEDICATION

What are these drugs used for?

• Atezolizumab, cisplatin, and etoposide are drugs given to treat some types of cancer including small cell lung cancer (SCLC).

How do these drugs work?

- Atezolizumab (a" te zoe 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.
- Cisplatin (sis-PLAT-in) and etoposide (ee-TOP-aw-side) are anticancer drugs that work by interfering with the genetic material of replicating cells and preventing an increase in the number of cancer cells.

INTENDED BENEFITS

• This treatment is being given to destroy and/or slow down the growth of cancer cells in your body. This treatment can help with controlling some of the symptoms the cancer may be causing and can also delay or prevent new symptoms from starting.

TREATMENT SUMMARY

How are these drugs given?

- Each medication will be given directly into the vein, intravenously (IV).
- The treatment will be given in 'cycles'. Each cycle length is 3 weeks.
- Your treatment plan starts with 4 cycles of combination immunotherapy and chemotherapy.

- For each of your first 4 cycles, you will have three medications given to you intravenously on Day 1, and two medications given to you intravenously on Days 2 and 3.
 - Day 1:
 - Atezolizumab is given first, over 30 to 60 minutes.
 - Cisplatin is given second, over approximately 30 minutes.
 - Etoposide is given third, over approximately 45 to 90 minutes.
 - Days 2 and 3:
 - Cisplatin is given first, over approximately 30 minutes.
 - Etoposide is given second, over approximately 45 to 90 minutes.
- After cycle 4 is completed, you will receive ongoing cycles of immunotherapy alone.
 - Day 1: Atezolizumab is given over approximately 30 minutes

The calendar outlines your overall treatment plan.

Cyc	les	1	to	4	

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Atezolizumab, Cisplatin & Etoposide	Cisplatin & Etoposide	Cisplatin & Etoposide	No treatment	No treatment	No treatment	No treatment
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment

This 21-day cycle will repeat 4 times, then you will start the next part of your treatment:

Cycles 5 and beyond:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Atezolizumab	No	No	No	No	No	No
	treatment	treatment	treatment	treatment	treatment	treatment
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
No treatment	No	No	No	No	No	No
	treatment	treatment	treatment	treatment	treatment	treatment
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
No treatment	No	No	No	No	No	No
	treatment	treatment	treatment	treatment	treatment	treatment

This 21-day cycle will repeat until your treatment is completed, as determined by your oncologist.

What will happen when I get my drugs?

- A blood test is done within one month of starting treatment.
- A blood test is also done each cycle, on or before the first day of each cycle. The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.
- You will see a physician or nurse practitioner every 3 weeks, before each cycle.
- Your very first treatment will take longer than other treatments because a nurse will be reviewing the possible side effects of your treatment plan and will discuss with you how to manage them. It is a good idea to bring someone with you to your first appointment.
- You will 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 will also need to take your anti-nausea drugs at home after therapy. It is easier to prevent nausea than to treat it once it has occurred, so follow directions closely.

OTHER INSTRUCTIONS

It is very important to report side effects immediately to your doctor. Do not manage side effects at home without first speaking with your doctor. Be aware that symptoms may be delayed and can develop months after your last dose.

- Tell your doctor if you have ever had an unusual or **allergic reaction** to atezolizumab, cisplatin, etoposide, or any drugs before starting this treatment.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of treatment.
- Atezolizumab, cisplatin, and etoposide 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 at least **5 months** after the last dose of atezolizumab. Tell your doctor right away if you or your partner becomes pregnant.
- Tell doctors or dentists that you are being treated with atezolizumab, cisplatin, and etoposide before you receive any treatment from them. You should carry the BC Cancer <u>wallet card</u> for atezolizumab to alert health providers.
- Do not receive any immunizations before discussing with your doctor.
- Sometimes, the nerve which allows you to hear can be affected by cisplatin. This could result in you experiencing "tinnitus" (ringing in the ears) or a change in your hearing. Report any of these problems to your doctor and/or nurse.

Other important things to know:

- Before you are given atezolizumab, talk to your doctor or pharmacist 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.
 - had an organ transplant, such as a kidney transplant.
 - have any other medical conditions.

Medication Interactions:

Other drugs may interact with atezolizumab, cisplatin, and etoposide. Tell a
member of your healthcare team if you are taking any other drugs as you may need
extra blood tests or your dose(s) may need to be changed. Check with your doctor
or pharmacist before you start or stop taking any new drugs including all prescription
and non-prescription medicines, steroids or other medicines that lower your immune
response, vitamins, and herbal supplements.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Atezolizumab 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 important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

What is the most important information I should know about SERIOUS SIDE EFFECTS?

- Atezolizumab 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 atezolizumab.
- *Tell* your doctor as soon as possible if you have any of serious side effects listed in the table below or 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
- nausea, vomiting
- fever, chills
- shortness of breath
- cough

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the NERVES Symptoms may include:	Very Common
 weakness of the legs, arms or face 	
 numbness or tingling in hands or feet 	
 lack of energy or dizziness 	
Inflammation of the INTESTINES (colitis)	Common
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 tendernessfever	
Inflammation of the SKIN	Common
Symptoms may include:	
 rash on your skin, mouth blisters, dry or peeling skin 	
Inflammation of the LUNGS (pneumonitis)	Common
Symptoms may include:	
shortness of breath	
chest pain	
coughing	

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the THYROID GLAND (hyperthyroidism,	Common
hypothyroidism)	
Symptoms may include:	
rapid heart beatweight loss or gain	
 weight loss or gain increased sweating 	
 hair loss 	
feeling cold	
constipation or diarrhea	
your voice gets deeper	
muscle aches	
changes in sleep patterns	
Infusion reactions	Common
Symptoms may include:	
 shortness of breath, wheezing or trouble breathing, cough, chest 	
 tightness dizziness, fainting, rapid or weak heartbeat 	
 dizziness, fainting, rapid or weak heartbeat itching, rash, hives, or feeling warm or flushed 	
 swelling of the throat, tongue, or face 	
 hoarse voice, throat tightness or trouble swallowing 	
 do not make enough hormone) Symptoms may include: weight loss increased sweating, hot flashes hair loss (includes facial and pubic) feeling cold headaches that will not go away or unusual headache changes in behavior such as less sex drive, being irritable or forgetful vision problems, dizziness or fainting excessive thirst and urination unusual tiredness or sleepiness 	
BLOOD SUGAR problems (type 1 diabetes mellitus)	Uncommon
Symptoms may include:hunger or thirst	
 a need to urinate more often 	
 weight loss 	
Problems in the PANCREAS Symptoms may include:	Uncommon
 abdominal pain 	
nausea and vomiting	

SERIOUS SIDE EFFECTS	How common is it?
 Inflammation of the LIVER (hepatitis) Symptoms may include: yellowing of your skin or the whites of your eyes dark urine, tiredness, nausea or vomiting, loss of appetite, pain on the right side of your stomach, or bruise easily 	Uncommon
Problems with MUSCLES Symptoms may include: • back pain • spasms • weakness • muscle pain	Rare
 Inflammation of the EYES Symptoms may include: changes in eyesight, blurry vision, double vision, or other vision problems eye pain or redness 	Rare
 Inflammation of the KIDNEYS (nephritis) Symptoms may include: changes in the amount or colour of your urine 	Rare

Other Side Effects of Treatment

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Allergic reactions to atezolizumab, cisplatin, and etoposide may rarely occur. Signs of an allergic reaction may include flushing, dizziness, confusion, rash, itching, fever, chills, swelling, chest discomfort, light headedness or breathing problems. Signs of allergic reaction can occur immediately or within one day after receiving treatment, and they can occur after the first dose or after many doses of treatment.	Tell your nurse if this happens while you are receiving treatment or contact your oncologist <i>immediately</i> if this happens after you leave the clinic.
Cisplatin and etoposide burn if they leak under the skin.	Tell your nurse <i>immediately</i> if you feel pain, burning, stinging, or any other change while the drug is being given.

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Your white blood cells may decrease after your treatment. They usually return to normal after your last 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 <i>immediately</i> 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.
Your platelets may decrease after your treatment. They usually 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: 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. Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). For minor pain, try acetaminophen (e.g., TYLENOL®) first, to a maximum of 4 g (4000 mg) per day.
Nausea and vomiting may occur after your treatment and may last after treatment. If you are vomiting and it is not controlled, you can quickly become dehydrated.	 You will be given a prescription for antinausea drug(s) to take before your treatment and at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. Drink plenty of fluids. Eat and drink often in small amounts. Try the ideas in <i>Practical Tips to Manage Nausea.</i>* Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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.	 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. 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</i>
	Sore Mouth.*
Tiredness or lack of energy may occur.	• Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Fatigue/Tiredness</i> – <i>Patient Handout</i> .*
Pain or tenderness may occur where the needle was placed in your vein.	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Loss of appetite and weight loss may occur and may persist after discontinuation of treatment.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite.</i> *
Taste alteration may occur.	Try the ideas in <i>Food Ideas to Cope with Taste and Smell Changes</i> .*
Hair loss is common with etoposide treatment and may begin within a few days or weeks of treatment. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. Hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change. Hair loss is rare with cisplatin and atezolizumab.	 Refer to Resources for Hair Loss and Appearance Changes – Patient Handout.* You may also want to: Apply mineral oil to your scalp to reduce itching. If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-brimmed hat and glasses.

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

THE FOLLOWING INFORMATION IS VERY IMPORTANT

SEE YOUR DOCTOR 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.
- **Diarrhea** or changes in **bowel habits**; black tarry stools; blood or mucous in the stool; abdominal pain.
- Changes in eyesight, eye pain, or redness.
- 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 an **infection** such as fever (over 38°C or 100°F 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 or tarry stools, blood in urine, pinpoint red spots on skin, or extensive bruising.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.
- Seizures or loss of consciousness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- 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.

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact: ______at telephone number:______

BC MEDICAL CER ALERT Provincial Health Services Authority NAME	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.
has received CHECKPOINT INHIBITOR IMMUNOTHERAPY: Immune-Mediated Adverse Reactions ALWAYS CARRY THIS CARD AND SHOW TO PHYSICIANS INCLUDING ANESTHETISTS	FOR MORE INFORMATION: BC Cancer - Abbotsford 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 Rev Aug 2018



To Whom It May Concern:

RE: ____

Medical Oncologist ____

Immunotherapy Regimen ____

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 <u>www.bccancer.bc.ca</u>.

BC Cancer Systemic Therapy Program Developed: 28 Nov 2017 Revised: www.bccancer.bc.ca Provincial Health Services Authority 1/2



BC CANCER CENTRES	CONTACT INFORMATION AND PROCESS
Abbotsford	Contact the patient's medical oncologist immediately by calling the Abbotsford Regional Hospital and Cancer Centre (ARHCC) switchboard at (604) 851-4700 and ask for the on-call medical oncologist (24-hour call system).
Kelowna	Between 8:30 am – 5:00 pm, call (250) 712-3900 (press "8" to speak to the Kelowna Centre receptionist) and have an oncologist paged. Outside these hours, call the Kelowna General Hospital switchboard at (250) 862-4000 and ask for the on-call medical oncologist.
Prince George	Between 8:30 am – 4:00 pm Monday to Friday, call (250) 645-7313. Outside these hours, go to the emergency department at the University Hospital of Northern British Columbia (UHNBC).
Surrey	Between 8:30 am – 4:00 pm Monday to Friday (except Statutory holidays), call the Nursing Phone Line at (604) 930-4053. Outside these hours, call the Surrey Memorial Hospital switchboard at (604) 581-2211 and ask for the Fraser Valley on-call medical oncologist.
Vancouver	Between 8:30 am – 4:30 pm Monday to Friday, call the Patient Nurse Line at (604) 877-6025. Outside these hours, call the inpatient unit at (604) 877-6000 and press 1, and ask for the on-call medical oncologist.
Victoria	Between 8:30 am – 4:30 pm Monday-Friday (except Statutory holidays), call (250) 519-5500, and press 1 then 4 to speak with a registered nurse. Outside these hours, call the Royal Jubilee Hospital switchboard at (250) 370-8000 and ask for the on-call medical oncologist.

BC Cancer Systemic Therapy Program Developed: 28 Nov 2017 Revised: www.bccancer.bc.ca Provincial Health Services Authority 2/2