



Provincial Health Services Authority

For the Patient: MYBLDF

Other Names: Treatment of Multiple Myeloma Using Bortezomib (Velcade®), Lenalidomide (REVLIMID®) and Dexamethasone

MY = **MY**eloma (tumour group)

B = **B**ortezomib (bor-tez-oh-mib)

L = **L**enalidomide (len-a-lid-oh-mide)

D = **D**examethasone (dex-a-meth-a-sona)

F = **F**irst-line treatment

Uses:

- **MYBLDF** is a code for drug treatment given for multiple myeloma.
- **MYBLDF** is for people with multiple myeloma that have not received treatment before and are not having a stem cell transplant.

How does it work?

- **MYBLDF** is a combination of three drugs that work together to treat multiple myeloma: bortezomib, lenalidomide, and dexamethasone.
- Bortezomib stops some enzymes in your body that help cells work properly and grow.
- Lenalidomide is thought to directly kill myeloma cells, stop myeloma cells from attaching to the bone marrow, stop blood vessels growing and giving blood to the myeloma cells, and help the immune system to kill the myeloma cells.
- Dexamethasone works with lenalidomide to kill myeloma cells.

Intended Benefits:

- **MYBLDF** may stop or slow down the growth of myeloma cells in your body. When you have this treatment, your multiple myeloma symptoms may get better or go away. This treatment may also stop new symptoms from starting.
- It will take many weeks or months of treatment before your healthcare team can determine if the treatment is working.

Treatment Plan:

- It is a combination of three drugs: bortezomib, lenalidomide, and dexamethasone.
- Bortezomib is injected under the skin. Lenalidomide and dexamethasone are pills that you swallow.
- Your treatment is made up of cycles, and **each cycle is 28 days or 4 weeks long** (days 1 to 28). All drugs start on Day 1 of each cycle. Changes to the treatment schedule may be needed to keep the 28 day length of each cycle.
 - It is important to ensure you understand when you should have each drug and how often.

For cycles 1 to 8 (approximately the first 8 months of treatment):

- You will receive **bortezomib** injections once per week for the first 3 out of 4 weeks (days 1, 8, and 15 of each cycle). There is no injection in week 4.
- For the first 3 weeks of each cycle, you will take **lenalidomide** by mouth (days 1 to 21 of each cycle). You will *not* take lenalidomide for the last 7 days of each cycle (days 22 to 28 of each cycle).
- You will take **dexamethasone** by mouth once per week, every week (days 1, 8, 15, and 22 of each cycle).
- Some people will take dexamethasone on a different schedule or take a similar type of drug called prednisone instead.

For cycles 9 and beyond:

- You will NOT receive bortezomib
- You will take lenalidomide and dexamethasone by mouth, in the same way you did in the first 8 cycles.

Start Date: _____

This calendar outlines what a cycle of treatment looks like:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Bortezomib* Lenalidomide Dexamethasone	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Bortezomib* Lenalidomide Dexamethasone	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Bortezomib* Lenalidomide Dexamethasone	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide
Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
Dexamethasone	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>None</i>

The 28-day cycle should not change unless needed to manage side effects. This 28-day cycle will repeat as long as the treatment continues to work and the side effects can be managed. *Bortezomib is only given for cycles 1 through 8.

Your blood test will usually be on Day 25 or 26 – your healthcare team will tell you.

It is important to take these drugs as prescribed by your healthcare team.

If you are thinking about stopping or changing how you take your cancer drugs, it is important that you contact your healthcare team right away before making changes.

Lenalidomide

- To take lenalidomide, you will be registered in a program called RevAid®.
- Lenalidomide can cause serious birth defects (problems) in unborn babies. The RevAid® program helps prevent lenalidomide from causing these birth defects by educating and monitoring you while you take this medication. Lenalidomide has a similar structure to the drug thalidomide.
- The program makes sure that people taking lenalidomide:
 - Use proper birth control and have pregnancy tests.
 - Do not donate blood or semen for four weeks after taking lenalidomide.
 - Do not share lenalidomide with other people.
- RevAid® does not let you to transfer your lenalidomide prescription from one pharmacy to another. If you want to do this, you need a new prescription from your doctor.
- When you pick up your lenalidomide, the pharmacist will talk to you about this drug.
- If someone else is picking up your lenalidomide, the pharmacist will phone you. The person picking up your lenalidomide will need to wait while the pharmacist talks to you.
- The pharmacist needs to do all of the RevAid® steps before they can give you, or the person picking up for you, the lenalidomide. This may take more time than usual.
- Lenalidomide is usually taken each day for 21 days (days 1-21), followed by a 7 day rest (when no lenalidomide is taken), unless otherwise directed by your doctor.
- Take lenalidomide at about the same time each day. It is best taken in the evening due to the fatigue side effect.
- Swallow capsule whole, do not crush or break
- Can be taken with or without food
- Return unused drug to the pharmacy. Do not keep lenalidomide at home or try to get rid of unused drugs at home.

Dexamethasone

- Usually given as 4 mg tablets (4 mg of dexamethasone per tablet, usually several tablets will make up one dose, for example 5 pills of 4mg dexamethasone = 20mg).
- Take dexamethasone once a week as a single dose with food in the morning. , or as directed by your healthcare team.
- Some patients may not be able to take dexamethasone
- Other patients may take prednisone instead

Labs:

- For the first 4 months, a blood test is usually done every 2 weeks.
- Blood tests are needed every 4 weeks, within 1 to 4 days of your next treatment cycle, to monitor your disease and side effects.
- Additional blood tests may be ordered each week to monitor you more closely.
- Your next cycle may be delayed, or your drug doses may be changed based on the blood test results. Results need to be reviewed by your healthcare team before each cycle is dispensed or treatment administered.
- Your every 4 weeks bloodwork should be drawn during the week off of lenalidomide and as instructed by your healthcare team.
- Once you have your blood test done, if you have lenalidomide refills call the pharmacy, or if you need a new prescription for lenalidomide call your doctor.

Serious Side Effects:

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are extra important because they are directly related to the common actions of these drugs.

- **Birth defects (*Teratogenicity*):** If lenalidomide is taken during pregnancy, it may cause severe birth defects or death to the unborn baby. Lenalidomide should never be used by anyone pregnant or who could become pregnant while taking the drug. Even a single dose may cause birth defects.

SIDE EFFECTS	MANAGEMENT
Normal 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. Both Lenalidomide and Bortezomib can cause low white blood cells.	To help prevent infection: <ul style="list-style-type: none">• Wash your hands often and always after using the bathroom.• Avoid crowds and people who are sick.• If you have a fever over 38°C or 100°F, call your healthcare team <u>immediately</u> (24 hours a day) or go <u>immediately</u> to your nearest Hospital Emergency and tell them that you are on chemotherapy. It is recommended you have a working thermometer at home.

SIDE EFFECTS	MANAGEMENT
<p>Normal platelets help your blood to clot normally after an injury (e.g., cut). When the platelet count is low, you may be more likely to bruise or bleed.</p> <p>Both Lenalidomide and Bortezomib can cause low platelets.</p>	<p>To help prevent bleeding problems:</p> <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. • 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 for you (e.g., ASA for your heart). • For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable. • If you develop black tarry stools, blood in your urine, pinpoint red spots on the skin, or prolonged nose bleeds report them immediately to your doctor or nurse.
<p>Blood clots may rarely occur. This is more likely to happen if you have had blood clots before. Signs to watch for include tenderness or hardness over a vein, calf tenderness, sudden onset of cough, chest pain, or shortness of breath. Lenalidomide can make the risk of a blood clot higher.</p>	<p>To help prevent blood clots:</p> <ul style="list-style-type: none"> • Keep active. • Drink plenty of fluids. • Avoid tight clothing. • Do not sit with your legs crossed at the knees. • Your doctor may ask you to take Aspirin 81 mg daily or an anti-coagulant to prevent this. • If you have signs of a blood clot call your healthcare team <u>immediately</u> (24 hours a day) or go <u>immediately</u> to your nearest Hospital Emergency and tell them that you are on chemotherapy.

Common Side Effects and Management:

SIDE EFFECTS	MANAGEMENT
Pain or tenderness may occur where bortezomib was injected.	<ul style="list-style-type: none">• Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Numbness, pain, tingling, or burning feelings in the feet and hands (<i>peripheral neuropathy</i>) may commonly occur with bortezomib. This may slowly return to normal once your treatments are 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, picking up small objects, walking, or have fallen.
Nausea and vomiting may occur with lenalidomide.	<ul style="list-style-type: none">• 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 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 Help Manage Nausea</i>. *
Fatigue is a common side effect of bortezomib and lenalidomide. Fatigue can also occur after the effects of dexamethasone wear off. As the number of cycles increases, fatigue may improve.	<ul style="list-style-type: none">• Refer to the pamphlet <i>Managing Fatigue (Tiredness)</i>. *• Take lenalidomide in the evening.• Sometimes a dose change may be required.• Do not drive a car or operate machinery if you are feeling tired.
Skin rash and/or itching may sometimes occur when taking lenalidomide, although in general it is not severe.	<ul style="list-style-type: none">• Minor rashes can be treated with diphenhydramine and/or steroid creams and lenalidomide can be continued.• Contact your doctor if rash worsens or is very irritating.

SIDE EFFECTS	MANAGEMENT
<p>Diarrhea (loose or watery bowel movements) may commonly occur with bortezomib and lenalidomide. If you have diarrhea and it is not controlled, you can quickly become dehydrated.</p>	<ul style="list-style-type: none"> • Diarrhea must be treated immediately with loperamide 2 mg tablets (e.g., IMODIUM®): • Take ONE tablet at the first sign of loose or more frequent stools than usual. • Then take ONE tablet every TWO hours until diarrhea has stopped for 12 hours • At night, you may take ONE tablet every FOUR hours (set your alarm) during the time you usually sleep. • Always keep a supply of loperamide (e.g., have 48 tablets on hand). You can buy loperamide at any pharmacy without a prescription. <p>To help diarrhea:</p> <ul style="list-style-type: none"> ▪ Drink plenty of liquids. ▪ Eat and drink often in small amounts. ▪ Avoid high fiber foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>.* • If diarrhea does not improve 24 hours after starting loperamide or lasts more than 36 hours, call your doctor.
<p>Constipation may sometimes occur with bortezomib and lenalidomide.</p>	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Suggestions for Dealing with Constipation</i>.* • Follow the instructions in <i>How to Treat Constipation Caused by Your Medications</i>*
<p>Headache 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. Check your temperature before taking acetaminophen to make sure you do not have a fever.
<p>Indigestion or heartburn with or without spasms of the intestines may sometimes occur.</p>	<ul style="list-style-type: none"> • Avoid fatty, fried, or spicy foods. • Talk to your doctor about taking antacids.
<p>Sugar Control may sometimes be affected in patients with diabetes.</p>	<ul style="list-style-type: none"> • Check your blood sugar regularly if you have diabetes.

SIDE EFFECTS	MANAGEMENT
Muscle, joint, or back pain may sometimes occur.	<ul style="list-style-type: none"> You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Check your temperature before taking acetaminophen to make sure you do not have a fever. Tell your doctor if the pain interferes with your activity.
Loss of appetite may sometimes occur.	<ul style="list-style-type: none"> Try the ideas in <i>Food Ideas to Help with Decreased Appetite*</i>
Increased energy may be due to dexamethasone and difficulty sleeping may be due to dexamethasone or lenalidomide	<ul style="list-style-type: none"> The days you take your dexamethasone you may feel as though you have extra energy. You may also have difficulty sleeping at night. Take the dexamethasone first thing in the morning to prevent difficulty sleeping at night. Talk to your doctor if you continue to have trouble sleeping.

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

Medication Interactions

Other drugs such as digoxin (LANOXIN®) may **interact** with lenalidomide. Tell your doctor if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your healthcare team before you start or stop taking any other drugs.

Other drugs and vitamin C supplements may interact with bortezomib. Green tea and preparations made from green tea should be avoided throughout the entire time that you are on bortezomib. These have been found to severely decrease the effectiveness of bortezomib, and might make it have no effect at all. Tell your doctor if you are taking any Natural Health Products. Check with your doctor or pharmacist before you start taking them.

Bone Health

Bone Health is important for people who have multiple myeloma and who are on treatment for multiple myeloma. Most people with multiple myeloma will also be given drugs to help with bone health. If you have questions about bone health and multiple myeloma, discuss them with your healthcare team.

If you experience symptoms or changes in your body that have not been described above but worry you, tell your doctor about them at the time of your next visit. If any symptoms are severe, contact:

_____ at telephone number _____

If you have symptoms that are severe or need emergency services, go to your local hospital's Emergency Department.