

Consent For VD-PACE

Condition For Which Treatment is Proposed:

1. I hereby authorize my physician, Dr _____, and/or such other staff physicians or resident physicians as my physician may designate, to administer to me (or the patient for whom I consent) the following chemotherapy consisting of:

**Bortezomib
Dexamethasone
Cisplatin
Doxorubicin
Cyclophosphamide
Etoposide**

The plan for my course of chemotherapy is for 1 cycle of chemotherapy.

2. My physician has discussed with me the items that are briefly summarized below:
 - a. The nature and purpose of the proposed therapy is to administer chemotherapy (drugs to fight my cancer, which may also have other effects on my body) by mouth and/or by vein or by other type of injection.
 - b. The risks of the proposed chemotherapy:

Chemotherapy may cause nausea, vomiting, loss of appetite, mouth sores, hair loss, fatigue, a lowering of the white blood cell count (which can lead to a serious infection), a lowered platelet count (which can lead to bleeding), and a decrease in my red blood cell count (which can lead to shortness of breath, a rapid heart beat or weakness). Due to these low blood counts, I may require red blood cell or platelet transfusions. My doctor will give me appropriate medications to try to decrease the severity of any side effects. Other side effects could occur, rarely death. It is important that I call my physician or nurse-coordinator with problems which occur during the course of my treatment. I always have the right to refuse chemotherapy at any time. It is possible that this chemotherapy may not be effective and my disease might progress.

Long-term side effects of chemotherapy can include injury to lungs, heart, liver and/or bladder. Acute leukemia can also develop as a result of chemotherapy.

Chemotherapy usually has an adverse effect on sperm and eggs and can cause me to be unable to have children. Chemotherapy can have harmful effects on an unborn child. If I am a woman, it is important to tell my physician if I think I may be pregnant. It is possible to conceive a child during treatment with chemotherapy. It is important that both men



and women who are being treated with chemotherapy and who are sexually active, fertile, and who have a fertile partner use a reliable form of birth control (birth control pills, a reliable barrier method or a hormonal implant. You (or the patient for whom you consent) may require **venipuncture** (putting a needle into a vein to remove blood or administer chemotherapy). The discomfort associated with venipuncture is a slight pinch or pinprick when the sterile needle enters the skin. The risks of venipuncture include mild discomfort and/or a black or blue mark at the site of the needle puncture. Less commonly, a small blood clot, infection or bleeding may occur at the needle puncture site. When chemotherapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the chemotherapy leaking outside the vein causing tissue irritation or damage.

The drugs which will be used for my planned chemotherapy and their specific side-effects:

Bortezomib: may cause numbness or tingling in fingertips and toes, low blood pressure, diarrhea, fever, heart rhythm, seizures, abnormal thoughts, blood clots, stomach bleeding.

Dexamethasone: may cause an irritation of the stomach lining (possibly leading to an ulcer which can bleed), high blood pressure, high blood sugar (or the aggravation of existing diabetes), serious infections and delayed wound healing, elevated white blood count, decrease in blood sodium, increased appetite, weight gain, rash, skin thinning, facial hair growth, acne, facial redness, bruises, menstrual changes, difficulty sleeping, muscle weakness, wasting, mood changes, seizures, fluid retention and swelling, cataracts, increased pressure behind the eye and bone weakening.

Cisplatin: Specific side effects of cisplatin include: numbness and tingling in the fingers and/or feet; decrease in hearing; decreased kidney function; decreased blood levels of certain salts in the body (magnesium, potassium, and calcium).

Doxorubicin: may cause heart damage when used for prolonged periods of time or in high doses. Due to the red color of doxorubicin, my urine may turn red for 1 to 2 days after I am given the drug; but this is harmless. Also seen is darkening of the nail beds and skin. In rare cases, the fingernails can become loose.

Cyclophosphamide: There is a small chance of causing urinary bladder (where urine is stored) irritation. This bladder irritation can cause pain and the appearance of blood in urine. However, this is almost always avoidable by drinking 8 to 10 glasses of water a day and emptying my bladder every 2 to 3 hours for 3 days, especially before bedtime. A metallic taste in the mouth and nasal congestion are commonly experienced immediately after the administration of the drug. Rarely, prolonged administration of the drug has been reported to cause scarring of the lungs which could cause me to experience coughing spells and shortness of breath and may not be reversible. Rarely, there may be severe or life-threatening allergic reactions.

Etoposide: Specific side effects of cisplatin include: numbness and tingling in the hands and/or feet; possible allergic-like reaction.

3. The medically reasonable alternative treatments and the risks associated with these alternative treatments have been described by my physician. These alternatives include no treatment, combinations of different chemotherapy drugs, or the same drugs given in



different doses or on a different schedule.

4. Without the proposed treatment, my disease may progress, it could remain stable or, rarely, improve.
5. I understand that during the course of this chemotherapy, unforeseen conditions may arise which could require the planned chemotherapy to be altered. All alterations to the planned chemotherapy will be discussed with me.
6. I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the proposed therapy.
7. I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the chemotherapy described above. I have had the opportunity to ask questions concerning my condition, the chemotherapy, the alternatives and risks, and all questions have been answered to my satisfaction.
8. I impose the following limitation(s) regarding my treatment (if none, so state):
9. I authorize the staff of The Milton S. Hershey Medical Center to preserve for scientific or teaching purposes any tissues or parts which may be removed in the course of this procedure, and to dispose of them.
10. I authorize the Milton S. Hershey Medical Center to permit other persons to observe this therapy with the understanding that such observation is for the purpose of advancing medical knowledge. I authorize The Milton S. Hershey Medical Center to obtain photographic or other pictorial representations of this therapy, and to use such representations for scientific or teaching purposes.
11. I certify that all blanks requiring insertion of information were completed before I signed this consent form.

_____ provided the information summarized above and obtained the
(fill in name) consent for the procedure

_____/_____/_____
(Patient's Signature) (Date) (Time)
(or signature of person consenting on behalf of the patient)

_____/_____/_____
(Optional: Witness to Patient's Signature) (Date) (Time)

_____/_____
(Physician's Signature) (Date)

