

Your cobimetinib (Cotellic®) and vemurafenib (Zelboraf®) ACTION PLAN

(to be filled out by a member of your oncology team)

Patient Name _____ Date _____
Full Name *Today's Date*

Side effects discussed _____

Key points _____

Financial Assistance

Genentech: A Member of the Roche Group
Patient Resource Center
1 (877) GENENTECH (436-3683)
<http://www.genentech-access.com/cotellic/patients>

TAKING THE MEDICATION

Cobimetinib (COTELLIC®) and vemurafenib (ZELBORAF®)

Combination for Melanoma

HOW TO TAKE YOUR MEDICATION:

- Zelboraf is taken by mouth twice a day.
- Cotellic is also taken by mouth, once a day.
- You **DO NOT** take Cotellic the last 7 days of each 28-day cycle.
- Both drugs can be taken with food or without food.
- The doses of the drugs may be lowered by your oncology team if you have a lot of side effects or other problems.

WHAT TO DO IF YOU MISS A DOSE:

- If you miss taking your Zelboraf dose and it is less than 4 hours until your next dose, **DON'T TAKE** the missed pills. If it is more than 4 hours until your next dose, take the dose.
- If you miss taking your Cotellic by more than 4 hours from the scheduled time, **DON'T TAKE** the missed pills. If it is within 4 hours of the scheduled time, take the dose.

Ways that can help you remember to take your pills: You can use a calendar, checking off each dose you take. You can also use a smartphone alarm, or put reminders on mirrors, doors, or your laptop. Be sure to bring your calendar to your visits with your oncology team.

If you or your partner becomes pregnant: Tell your oncology team right away if you or your partner becomes pregnant or think you are pregnant while on these medications as they can harm a developing fetus. Be sure to use effective birth control if you are a woman of child-bearing age or a man who is sexually active.

Common side effects of this combination therapy:

Even small side effects could be serious and you should report ALL of them to your oncologist's office. The most common side effects of taking Cotellic/Zelboraf are...

- Diarrhea
- Fatigue
- Skin rash
- Nausea
- Vomiting
- Fever
- Joint aches and pains
- A skin reaction to sunlight

SIGNS OF AN ALLERGIC REACTION TO THE MEDICATIONS:

Stop taking your medications and get medical help immediately if you have any of these signs of a serious allergic reaction:

- A rash or redness all over your body
- Trouble breathing or swallowing
- Swelling of the face, lips, or tongue
- Tightness in the throat or a hoarse voice
- Feeling faint
- A fast heartbeat.

You may want to keep a notebook as your treatment diary and write down when you take your pills, how many pills you take, and if you have any side effects. Be sure to bring this treatment diary to your visits with your oncology team.

IMPORTANT SIDE EFFECTS

Your oncology team may discuss some side effects of Cotellic/Zelboraf that can lead to serious problems if they aren't taken care of right away. These sections give information about possible symptoms, what you should tell your oncology team, when you should get medical help immediately, and any steps you can take to help ease the symptoms.

FEVER, WITH OR WITHOUT CHILLS

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Report immediately to your oncologist's office

What are the symptoms?

Temperature of 100.4°F or higher or chills without a fever

What you should tell your oncology team member:

- What your temperature reading is high.
- When the fever started and how long it has lasted.
- What type of thermometer you used to take your temperature.
- If you have chills, stomach or breathing problems, feel dizzy when you stand up quickly, feel very tired, and/or have not been going to the bathroom (urinating) as much as you usually do.
- How much and what you have been drinking over the past 24 hours.
- If you have recently been around people with colds/flu or animals, or if you have traveled nationally or internationally.



Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- A fever over 104.0°F.
- Any fever and passing out or feeling faint.

Managing Your Side Effects

- If approved by your oncologist's office, take over-the-counter pain relievers such as acetaminophen (Tylenol®) or ibuprofen (Advil®, Motrin®) every 6 hours until the fever goes away. Don't take more than 3000 mg a day of acetaminophen or 2400 mg a day of ibuprofen.
- Take a cool or slightly warm bath.
- Put cool compresses or a cold pack on your forehead and neck.
- Drink water and other liquids such as juice and sports drinks (Gatorade®, Powerade®, and Pedialyte®) or suck on popsicles to prevent dehydration.

SKIN CHANGES

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Report immediately to your oncologist's office

What are the symptoms?

- A reddish bump that bleeds or doesn't heal
- Changes in the size or color of a mole
- Redness of the skin that looks like a sunburn
- Itching
- A rash
- A new wart
- A skin sore

What you should tell your oncology team member:

- When you first noticed the skin change or itching.
- What the "rash" looks like – (eg, flat, bumpy, acne-like, etc.).
- Where and how much of your body the rash covers.
- If the skin change is making it difficult for you to get dressed, eat, or sleep.
- If you have had any skin problems in the past.
- If you have been using a new soap or been around new chemicals or animals recently.
- What the rash looks like (eg, does it look like acne, hives).

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- A rash that covers a large part of your body or that is quickly getting worse.
- Blisters (on your skin or in your mouth or genital area) that are peeling. Skin that looks infected (red streaks, pus, or draining).
- Any rash that is accompanied by a fever.

Managing Your Side Effects

- Avoid soap. Instead, use gentle, non-soap cleansers such as Cetaphil®.
- Avoid hot baths.
- Avoid tight clothing and shoes.
- Keep your fingernails short to stop yourself from scratching.
- Apply a moisturizer daily.
- Protect your skin from the sun by wearing sunscreen (30 SPF or higher), a hat, and UV-protective clothing and sunglasses. Don't forget your hands and face.
- Your oncology team may tell you to take an antihistamine or pain reliever to reduce the pain and itching.
- Have regular skin exams before and during treatment.

EYE AND VISION PROBLEMS

Cobimetinib (COTELLIC®) and vemurafenib (ZELBORAF®)

Combination for Melanoma

Report immediately to your oncologist's office

What are the symptoms?

- Eye pain, swelling, or redness
- Blurred vision
- Partial or full loss of vision
- Seeing halos or other vision problems

What you should tell your oncology team member:

- When you started to have vision problems, how severe they are, and how long they have lasted.
- If you have had any vision problems in the past, such as dry eyes or glaucoma.
- If you recently have had an eye injury, started on a new medication, or been exposed to chemicals.
- If you wear contact lenses.
- If you have diabetes.
- If you have any other symptoms, such as a headache, vomiting, or nausea.
- When you last had an eye examination.

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- Sudden and severe symptoms, such as sudden vision changes or vision loss, eye pain, redness, or unusual sensitivity to sunlight and glare.

Managing Your Side Effects

- Follow your oncology team's instructions for getting eye exams at the eye doctor.
- Wear sunglasses to protect your eyes from the sun's damaging rays.
- If you wear contact lenses, be careful to follow guidelines for keeping your eyes hydrated well and for cleaning, wetting, and replacing lenses.
- If you have diabetes, keep your blood glucose level under good control to reduce the risk of eye disease.
- Follow a healthy lifestyle to take care of your eyes as well as your body.

POTENTIAL HEART PROBLEMS

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Report immediately to your oncologist's office

What are the symptoms?

- Chest pain
- Changes in energy level or shortness of breath while resting or when active
- Frequent coughing or wheezing (making a whistling sound while breathing)
- Swelling in the legs or ankles
- Dizziness
- Feeling that your heart is skipping a beat, fluttering, or beating too hard or fast
- Fainting
- Excessive sweating

What you should tell your oncology team member:

- When you started to have any of these symptoms, how severe they are, and how long they have lasted.
- If you had any of these symptoms before you started Cotellic/Zelboraf.
- If you have been told in the past that you have a heart condition.

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- Sudden onset of these symptoms.
- Any chest pain.
- Difficulty breathing.
- Fainting.

Managing Your Side Effects

- Follow your oncology team's instructions for tests on your heart.
- Be sure to drink enough liquids to stay hydrated.
- Avoid drinking alcohol or taking drugs that affect the heart or brain (such as marijuana, sleeping pills, or stimulants) unless told to do so by your healthcare providers.
- Follow a healthy lifestyle to take care of your heart as well as your body.
- If you are on any medications for your blood pressure or your heart, be sure to take them as ordered and not miss any doses.

JOINT PAIN, SWELLING, OR STIFFNESS

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Combination for Melanoma

Report immediately to your oncologist's office

What are the symptoms?

Joint pain, swelling, and/or stiffness

What you should tell your oncology team member:

- When these symptoms started, what causes them, and how long they lasted.
- Which joints are affected.
- If you have ever had any joint problems in the past.

Red flags – Call your oncologist's office immediately – if they are not available, go directly to the Emergency Room.

- Sudden or severe onset of joint pain, swelling, or stiffness.
- If the joint looks deformed.
- If you can't place weight on the joint (such as your ankle) or use it at all.

Managing Your Side Effects

- With the approval of your oncologist's office, take anti-inflammatories/pain relievers such as aspirin, ibuprofen (Advil®, Motrin®), or naproxen (Aleve®) to relieve pain and stiffness. Ask your oncology team member about how much to take.
- Apply an ice pack to swollen joints for 15 minutes several times a day.
- Keep the joint above your heart whenever you can to reduce swelling.
- Use elastic wrap or tape on the joint to support it.
- Avoid activities that cause pain, but try to maintain some exercise routine, if possible.

OTHER SYMPTOMS TO LOOK OUT FOR

Below are other symptoms you may experience when taking Cotellic®/Zelboraf®. Please call the office if you develop any of these symptoms. Call your oncologist's office immediately if you develop any of the red-flag symptoms. If they aren't available immediately, go to the Emergency Room.

	Symptoms	Red flags (Signs that something serious is going on that needs immediate attention)
	Bowel movement changes or constipation (infrequent bowel movements)	If your stools are black or red plus you have pain and fever
	Bruising (black and blue marks)	Excessive bleeding gums, nosebleeds that won't stop
	Chills (shaking) or feeling cold when you don't have a fever	—
	Diarrhea (loose or frequent stools)	Severe pain in the stomach; stools that are bloody or that look like tar
	Dizziness (lightheadedness)	If you faint
	Fatigue (feeling weak or tired)	If you faint
	Headaches	If you have a very painful headache (the "worst headache of your life"), head pain that doesn't go away after a few hours, or head pain with fever, neck pain or stiffness, and/or rash
	Muscle aches, pains, spasms, or weakness	If these symptoms occur along with dark, reddish urine
	Nausea (upset stomach)	If you have any uncontrolled nausea that is keeping you from eating and/or drinking
	Reactions to the sun (severe sunburn; red, painful, dry itchy skin that is hot to the touch; sun rash; skin irritation; bumps; thickened, dry, wrinkled skin)	If you have redness all over your body, blisters on your skin or in your mouth, and/or your skin peels
	Shortness of breath (trouble breathing)	<ul style="list-style-type: none"> • If you have any trouble breathing at rest • If you have shortness of breath and chest pain and/or fainting
	Skin inflammation (swelling) in areas treated with radiation	—
	Stomach pain	If you have sudden severe pain or tenderness in the stomach, blood in the stool, you're vomiting blood, and/or your skin or eyes are turning yellow
	Swelling in your arms or legs	If you have a warm, tender spot on your leg that doesn't get cooler when you put ice on it, and/or if the spot is itchy or tingles, and/or the pain gets worse for no reason
	Thirst, more than usual	If you have great thirst along with feeling very tired, a lack of sweating on a hot day, weakness, dizziness, nausea

OTHER SYMPTOMS TO LOOK OUT FOR

(Continued)

	Symptoms	Red flags (Signs that something serious is going on that needs immediate attention)
	Urine, dark or reddish	If you have bright red blood in your urine. If at the same time, if you also feel dizzy, have pain in the back or side, a taste like metal in your mouth, feel sick to your stomach, are vomiting, feel very tired, have shortness of breath, and/or swelling of arm, legs, or the face
	Urination, less than usual	If you also have blood in the urine, swelling of the ankles, and don't feel like eating
	Urination, more than usual	—
	Vaginal bleeding	If you are bleeding for many hours or bleeding a lot (more than one pad an hour) and have severe stomach pain
	Vomiting (throwing up)	If you go more than 24 hours without being able to hold down foods or liquids, and/or you vomit blood or you have severe stomach pain
	Vomiting (throwing up) blood	If you throw up any blood
	Weakness	<ul style="list-style-type: none"> • If weakness is on the face or one side of body plus you have numbness, slurred speech, confusion, drooping in the face • If weakness is all over the body and you feel very tired and even faint, have a fever, or your heart is racing

PATIENT RESOURCES

ADDITIONAL INFORMATION RESOURCES

AIM at Melanoma Foundation (Ask an Expert program, patient symposia, drug resources, etc)
<https://www.aimatmelanoma.org/>

American Cancer Society: Targeted therapy for melanoma skin cancer

<https://www.cancer.org/cancer/melanoma-skin-cancer/treating/targeted-therapy.html>

FINANCIAL ASSISTANCE

Genentech: A Member of the Roche Group

Patient Resource Center

1 (877) GENENTECH (436-3683)

<http://www.genentech-access.com/cotellic/patients>

Cancer Financial Aid Coalition

Facilitates communication, educates and advocates for patients.

www.cancerfac.org

Centers for Medicare and Medicaid Services (CMS)

Apply to determine if you are eligible for government assistance.

www.cms.gov or www.medicare.gov

800-633-4227

Lazarex Foundation

Provides assistance with travel costs for clinical trial participation. Ask your social work counselor for a referral if you have been consented to a clinical trial for melanoma.

www.lazarex.org

NeedyMeds

Database to search for free or low-cost medications, help with medical transportation and other resources.

www.needymeds.org

Patient Advocate Foundation

Provides assistance with mediation, financial stability, and other assistance. Funds subject to availability. Patient must meet their eligibility for financial assistance.

www.patientadvocate.org

800-532-5274

The Sam Fund for Young Adult Survivors of Cancer

Assists cancer survivors ages 21-39 with their transition into post-treatment life. This program distributes grants and scholarships in an effort to enable survivors to pursue goals.

www.thesamfund.org

info@thesamfund.org

PRESCRIPTION ASSISTANCE

CancerCare Co-Payment Assistance Foundation

Helps with the cost of medication. Availability of funds for patients with Stage IV melanoma subject to availability.

www.cancercarecopay.org

1-866-552-6729

Medicine Assistance Tool

Database to search for patient assistance resources offered by pharmaceutical companies.

www.medicineassistancetool.org/

Patient Advocate Foundation Co-Pay Relief

Provides direct financial support to patients who medically qualify. Availability of funds for patients with Stage IV melanoma subject to availability.

www.copays.org

1-866-512-3861

Good Days

Formerly known as the Chronic Disease Fund. Provides assistance with insurance co-pays, and prescription medications. Availability of funds for patients with Stage IV melanoma subject to availability.

www.mygooddays.org

HealthWell Foundation

For patients who cannot afford insurance premiums, co-payments, co-insurance, or other out-of-pocket health care costs. Availability of funds for patients with Stage IV melanoma subject to availability. Patient must also meet eligibility for financial assistance.

www.healthwellfoundation.org or

grants@healthwellfoundation.org

1-800-675-8416

The Assistance Fund, Inc

Provides prescription copay and financial assistance, including health insurance premiums. Availability of funds for patients with Stage IV melanoma subject to availability.

www.theassistancefund.org

1-855-845-3663

PAN Foundation

Provides financial assistance to cover out-of-pocket treatment costs. Availability of funds for patients with Stage IV melanoma subject to availability.

www.panfoundation.org

1-866-316-PANF (7263)

Patient Assistance Program

Comprehensive database of patient assistance programs offering free medications.

www.rxassist.org

info@rxassist.org

HOUSING

American Cancer Society – Hope Lodge

Provides free housing during treatment appointments. Requires a referral from your social worker.

www.cancer.org/

1-800-227-6333

TRANSPORTATION (AIR AND GROUND)

Medicaid

Ground transportation only. Sets up rides and provides mileage reimbursement for Medicaid patients only.

1-877-633-8747

Mercy Medical Angels

Provides free medical transportation (flights, gas cards, bus and train tickets) for patients with financial needs who need to travel more than 50 miles. Patients must meet their eligibility for financial assistance.

www.mercymedical.org/

Pilots for Patients

Provides free flights to people in need of medical treatment. Patient must be medically stable to fly and be ambulatory. Ask your social worker about a referral.

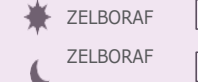
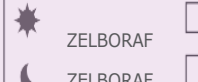
www.pilotsforpatients.org

318-322-5112

Cotellic/Zelboraf Dosing Calendar

START DATE: _____

_____ day _____ day _____ day _____ day _____ day _____ day _____ day
 Date: _____ Date: _____ Date: _____ Date: _____ Date: _____ Date: _____ Date: _____

WEEK 1	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____
	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>
WEEK 2	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____	_____ day Date: _____
	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>
WEEK 3	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____
	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>
WEEK 4	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____	COTELLIC _____ day Date: _____
	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>	 ZELBORAF <input type="checkbox"/> ZELBORAF <input type="checkbox"/>

For a missed dose of Cotellic: If 4 hours or less from scheduled dosing time, take the dose; more than 4 hours, hold that dose and take the next scheduled dose at the normal time.
 A missed dose of Zelboraf can be taken up to 4 hours prior to the next dose.
 Do not take a double dose to make up for a missed dose.

For more information see Genentech USA, Inc. (2016). Cotellic® (cobimetinib) [Package Insert]. Retrieved from: https://www.gene.com/download/pdf/cotellic_prescribing.pdf.
 Also see supplemental materials from Larkin, J., Ascierto, P. A., Dreno, B., Atkinson, V., Liszkay, G., Maio, M., . . . Ribas, A. (2014). *New England Journal of Medicine*, 371, 1867–1876.

For more information see Genentech USA, Inc. (2016). Zelboraf® (vemurafenib)[Package Insert]. Retrieved from https://www.gene.com/download/pdf/zelboraf_prescribing.pdf.