



Getting started with POMALYST

POMALYST® (pomalidomide) is a prescription medicine, taken along with the medicine dexamethasone, used to treat people with multiple myeloma who have previously received at least 2 medicines to treat multiple myeloma, including a proteasome inhibitor and lenalidomide, **and** whose disease has become worse during treatment or within 60 days of finishing the last treatment. It is not known if POMALYST is safe and effective in children.

POMALYST is only available through a restricted distribution program, POMALYST REMS®.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-7.

Important Safety Information

What is the most important information I should know about POMALYST?

Before you begin taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS® program. Before prescribing POMALYST, your healthcare provider (HCP) will explain the POMALYST REMS program to you and have you sign the Patient-Physician Agreement Form.

POMALYST can cause serious side effects, including:

- **Possible birth defects (deformed babies) or death of an unborn**

baby. Females who are pregnant or plan to become pregnant must not take POMALYST.

- **POMALYST is similar to the medicine thalidomide (THALOMID®),** which is known to cause severe life-threatening birth defects. POMALYST has not been tested in pregnant females. POMALYST has harmed unborn animals in animal testing.

- **Females must not get pregnant** for at least 4 weeks before starting POMALYST, while taking POMALYST, during any breaks (interruptions) in your treatment with POMALYST, and for at least 4 weeks after stopping POMALYST.

- Females who can become pregnant:

- Must have pregnancy tests weekly for 4 weeks once treatment has started, then every 4 weeks if your menstrual cycle is regular or every 2 weeks if your menstrual cycle is irregular. If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.
- Must agree to use 2 different forms of effective birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in treatment, and for at least 4 weeks after stopping POMALYST. Talk with your HCP to find out about options for acceptable forms of birth control that you may use to prevent pregnancy.

- **If you become pregnant while taking POMALYST, stop taking it right away and call your HCP.** If your HCP is not available, you can call Celgene Customer Care Center at 1-888-423-5436. Healthcare providers and patients should report all cases of pregnancy to FDA MedWatch at 1-800-FDA-1088, and Celgene Corporation at 1-888-423-5436. There is a pregnancy exposure registry that monitors the outcomes of females who take POMALYST during pregnancy, or if their male partner takes POMALYST and they are exposed during pregnancy. You can enroll in this registry by calling Celgene Corporation at the phone number listed above.

- **POMALYST can pass into human semen.** Males, including those who have had a vasectomy, must always use a latex or synthetic condom during any sexual contact with a pregnant female or a female that can become pregnant while taking POMALYST, during any breaks (interruptions) in your treatment with POMALYST, and for at least 4 weeks after stopping POMALYST.

- **If a female becomes pregnant with your sperm, you should call your HCP right away.** The baby may be exposed to POMALYST and may be born with birth defects.

- Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your HCP if you have unprotected sexual contact with a female who is or could become pregnant.

- Do not donate sperm while taking POMALYST, during any breaks (interruptions) in your treatment, and for at least 4 weeks after stopping POMALYST.

- **Do not donate blood** while you take POMALYST, during any breaks (interruptions) in your treatment, and for at least 4 weeks after stopping POMALYST. If someone who is pregnant gets your donated blood, her baby may be exposed to POMALYST and may be born with birth defects.

Important Safety Information (continued)

- **Blood clots in your arteries, veins, and lungs; heart attack; and stroke. Most people who take POMALYST will also take a blood thinner medicine to help prevent blood clots.**
 - Before taking POMALYST, tell your HCP if you have had a blood clot in the past, if you have high blood pressure or hyperlipidemia (high level of fat in your blood), or if you smoke. Tell your HCP about all the medicines you take because certain other medicines can also increase your risk for blood clots.
 - **Call your HCP or get medical help right away if you get any of the following during treatment with POMALYST:**
 - (1) signs or symptoms of a blood clot in the lung, arm, or leg**, including shortness of breath, chest pain, or arm or leg swelling;
 - (2) signs or symptoms of a heart attack**, including chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen); feeling sweaty; shortness of breath; feeling sick; or vomiting; or
 - (3) signs or symptoms of stroke**, including sudden numbness or weakness, especially on one side of the body; severe headache or confusion; or problems with vision, speech, or balance.

Who should not take POMALYST?

- Do not take POMALYST if you are pregnant, plan to become pregnant, or become pregnant during treatment with POMALYST. **See “What is the most important information I should know about POMALYST?”**

What should I tell my healthcare provider (HCP) before taking POMALYST?

- If you smoke cigarettes (POMALYST may not work as well in people who smoke), have any other medical conditions, or are breastfeeding. Do not breastfeed during treatment with POMALYST—it is not known if POMALYST passes into breast milk and can harm the baby.
- **Tell your HCP about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. POMALYST and other medicines may affect each other, causing serious side effects. Talk with your HCP before taking any new medicines.

How should I take POMALYST?

Take POMALYST exactly as prescribed and follow all the instructions of the POMALYST REMS program.

- Swallow POMALYST capsules whole with water 1 time a day. **Do not break, chew, or open capsules.**
- Take POMALYST at the same time each day **with or without food.**
- If you are on hemodialysis, take POMALYST after hemodialysis on hemodialysis days.
- Do not open POMALYST capsules or handle them any more than needed. If you touch a broken POMALYST capsule or the medicine in the capsule, wash the area of your body right away with soap and water.

Important Safety Information (continued)

- If you miss a dose of POMALYST and it has been less than 12 hours since your regular time, take POMALYST as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do **not** take 2 doses at the same time.
- If you take too much POMALYST, call your healthcare provider (HCP) right away.
- **Do not share POMALYST with other people.** It may cause birth defects and other serious problems.

What are the possible side effects of POMALYST?

- See “What is the most important information I should know about POMALYST?”
- **POMALYST can cause serious side effects, including:**
 - **Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia) are common with POMALYST, but can also be serious.** You may need a blood transfusion or certain medicines if your blood counts drop too low. Your blood counts should be checked by your healthcare provider (HCP) weekly for the first 8 weeks of treatment and monthly after that.
 - **Severe liver problems, including liver failure and death.** Your HCP should do blood tests to check your liver function during your treatment with POMALYST. Tell your HCP right away if you develop any of the following symptoms: yellowing of your skin or the white parts of your eyes (jaundice); dark or brown (tea-colored) urine; pain on the upper right side of your stomach area (abdomen); bleeding or bruising more easily than normal, or feeling very tired.

- **Severe allergic and skin reactions.** Call your HCP if you have any symptoms of an allergic reaction, including: swelling of your lips, mouth, tongue, or throat; trouble breathing; or skin reaction.
 - **Dizziness and confusion.** Avoid taking other medicines that may cause dizziness and confusion during treatment with POMALYST. Avoid situations that require you to be alert until you know how POMALYST affects you.
 - **Nerve damage.** Stop taking POMALYST and call your HCP if you develop numbness, tingling, pain, or a burning sensation in your hands, legs, or feet.
 - **New cancers (malignancies).** New cancers, including certain blood cancers (acute myelogenous leukemia or AML) have been seen in people who received POMALYST. Talk with your HCP about your risk.
 - **Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your HCP may do blood tests to check you for TLS.
- The most common side effects of POMALYST include tiredness, weakness, constipation, nausea, diarrhea, shortness of breath, upper respiratory tract infection, back pain, and fever.
 - These are not all the possible side effects of POMALYST. Your HCP may tell you to stop taking POMALYST if you develop certain serious side effects during treatment. Call your HCP for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Welcome

You're taking an important step in treating your relapsed multiple myeloma with POMALYST. While your healthcare team is your best source of information, this guide provides answers to common questions you may have.

Table of contents

- Overview of relapsed multiple myeloma 11
- Learn more about POMALYST 17
- Clinical trial of POMALYST 20
- POMALYST REMS® Program 23
- POMALYST dosing 27
- Learn about side effects of POMALYST 35
- Celgene Patient Support® 39
- Glossary 45

Overview of relapsed multiple myeloma

The more you know about multiple myeloma, the more involved you can be when making decisions about your care with your healthcare team.

Why am I changing medications?

Your doctor may have told you that your multiple myeloma (MM) has come back, also known as a relapse. This means your MM is no longer responding to the medications you're taking. For this reason, it may be time to change your treatment.

The following information may help you understand some of the ways your MM is changing.

Empower yourself

Ask questions and stay involved in your treatment.

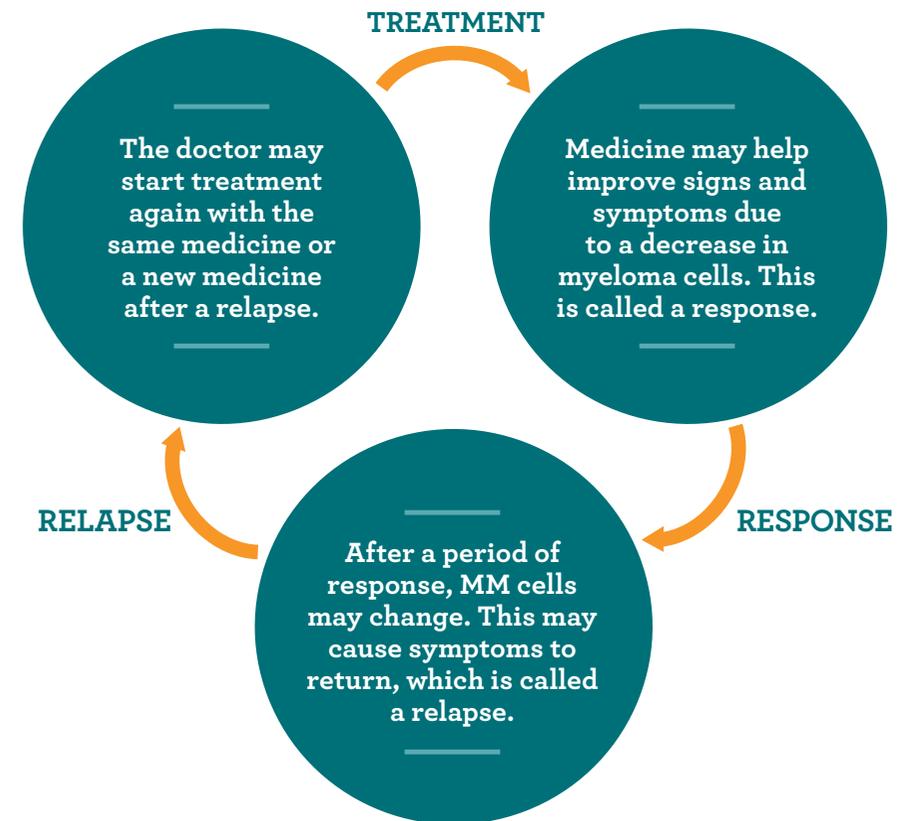
Why does multiple myeloma keep coming back?

Multiple Myeloma is currently an incurable disease. Treatment can significantly reduce the number of myeloma cells. But these cells can stop responding to medication, which allows them to multiply uncontrollably. This is called a relapse and starts the cycle of MM once more.

It's common for someone with MM to go through several of these cycles.

Since myeloma cells may change and cause medications to stop working, your doctor will likely change your treatment plan to try to get them under control.

Understanding the cycle of multiple myeloma



It's important for you to adhere to your prescribed MM medicine, so make sure to discuss any side effects with your healthcare team.

What is multiple myeloma?

As you probably know, multiple myeloma (MM) is a chronic cancer of **plasma cells** that live in your **bone marrow**. Healthy plasma cells are a critical part of the immune system and play an important role in fighting infection. In MM, cancerous plasma cells build up and cause damage, including:



Bone damage can cause bone pain and weak or broken bones



Low red blood cell counts (anemia) can cause weakness, shortness of breath, and dizziness



Excess calcium in the blood, a frequent result of myeloma cell activity, can put extra strain on the kidneys



Kidney problems can cause weakness and leg swelling



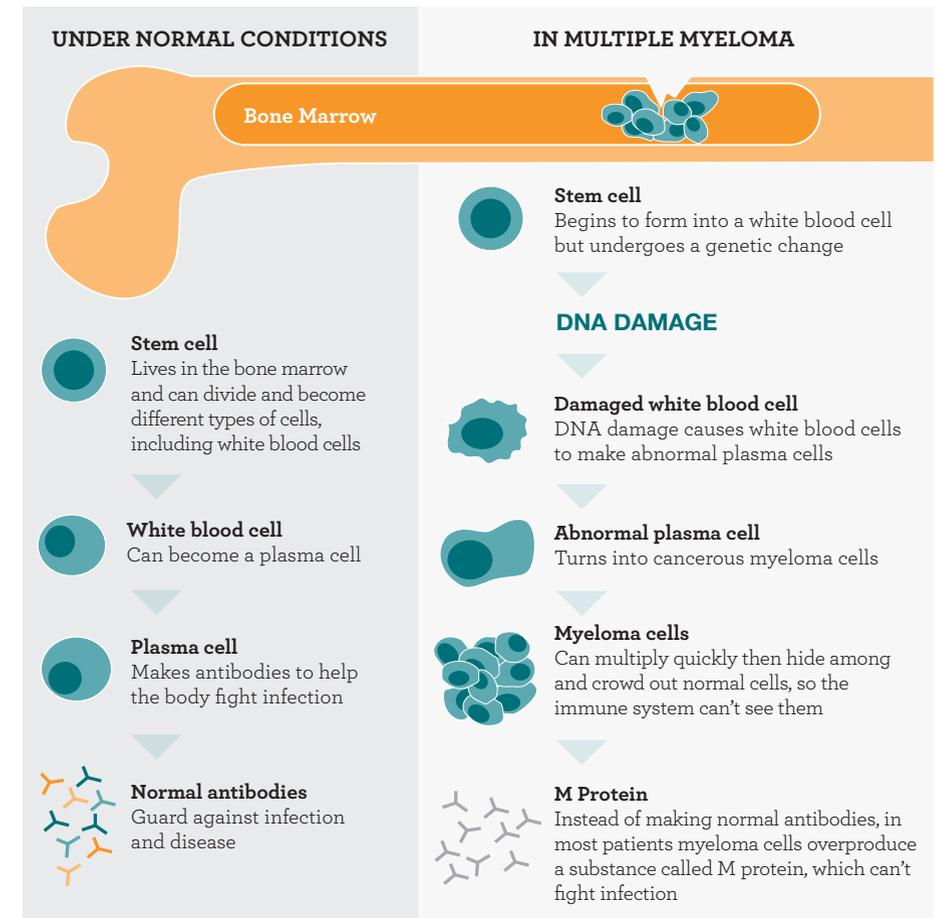
Low white blood cell count (leukopenia) can make it harder to fight infections

Treatment is important

There is no cure for MM, but a long-term treatment strategy can help you manage it.

How multiple myeloma develops

The bone marrow makes different types of immune cells, including plasma cells. In multiple myeloma, plasma cells become cancerous. These cells can disguise themselves to look harmless so they go undetected and multiply, crowding out healthy cells in the marrow. Myeloma cells also release chemical messengers that can stop healthy immune cells from working.



Learn more about POMALYST

POMALYST is used with dexamethasone to treat relapsed multiple myeloma in people who have received at least 2 medicines, including REVLIMID® (lenalidomide) and a proteasome inhibitor.

Learn more about POMALYST

Pomalyst REMS®

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Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide, and Important Safety Information on pages 2-7.

 **Pomalyst**
(pomalidomide) capsules
1 · 2 · 3 · 4 mg

Get to know POMALYST



POMALYST, taken with dexamethasone, is approved to treat multiple myeloma (MM) in patients whose disease has become worse while treating with a proteasome inhibitor and REVLIMID® (lenalidomide)



POMALYST is not a traditional chemotherapy, injection, or infusion—it's an immune-modulating therapy



POMALYST is a once-daily pill taken at home or wherever is convenient for you. POMALYST is approved to be taken along with dexamethasone.

POMALYST gives you multiple ways to fight multiple myeloma—even after REVLIMID® (lenalidomide) stops working

POMALYST was shown to work in 3 ways in animal models and **in vitro***:

***In vitro**: In a test tube or glass; outside of a living organism.



STRIKE

Targets and kills myeloma cells (with dexamethasone)—even those resistant to REVLIMID



STIMULATE

Helps your immune system recognize and destroy myeloma cells



STARVE

Helps prevent new myeloma cell growth by reducing blood supply

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What is the most important information I should know about POMALYST?

Before you begin taking POMALYST, you must read and agree to all of the instructions in the POMALYST REMS® program. Before prescribing POMALYST, your healthcare provider will explain the POMALYST REMS program to you and have you sign the Patient-Physician Agreement Form.

POMALYST can cause serious side effects, including:

- **Possible birth defects (deformed babies) or death of an unborn baby.** Females who are pregnant or plan to become pregnant must not take POMALYST.

About the Study

A study of 455 patients compared the efficacy and safety of POMALYST with low-dose dexamethasone versus high-dose dexamethasone alone, as a treatment for multiple myeloma (MM) in people who had taken at least 2 prior therapies, including a proteasome inhibitor and REVLIMID® (lenalidomide), and their disease has become worse during treatment or within 60 days of finishing the last treatment (defined as relapsed/refractory).

The study evaluated:

- Overall Survival (OS)—the length of time patients lived since the start of treatment
- Progression-Free Survival (PFS)—how long a patient lives without the disease getting worse

Patients were divided into 2 groups:

- The first group took POMALYST with low-dose dexamethasone
- The second group took high-dose dexamethasone alone

Patients who took POMALYST with dexamethasone experienced:

Overall Survival (OS)

More patients taking POMALYST with low-dose dexamethasone lived longer compared to high-dose dexamethasone alone

Progression-Free Survival (PFS)

Patients receiving POMALYST with low-dose dexamethasone had a longer PFS compared to patients taking high-dose dexamethasone alone

Pomalyst won't work for everyone. Individual results may vary.

Important Safety Information (continued)

What are the possible side effects of POMALYST?

- The most common side effects of POMALYST include tiredness, weakness, constipation, nausea, diarrhea, shortness of breath, upper respiratory tract infection, back pain, and fever.

POMALYST REMS^{®*} Program

*Risk Evaluation and Mitigation Strategy

Every patient who takes POMALYST must enroll in the POMALYST REMS[®] program.

POMALYST REMS® Program

How to receive your first prescription for POMALYST® (pomalidomide)



For each of your following prescriptions, you will need to follow a similar process. For full detailed information about the POMALYST REMS® program requirements, please visit www.CelgeneRiskManagement.com or review the Patient Guide to POMALYST REMS® program.



For each of your following prescriptions, pregnancy tests will be required depending on your ability to get pregnant. For full detailed information about the POMALYST REMS® program requirements, please visit www.CelgeneRiskManagement.com or review the Patient Guide to POMALYST REMS® program.

POMALYST dosing

POMALYST is prescribed differently based on your lab results or how you're feeling. Your doctor or healthcare provider will prescribe you a specific dose suited to your needs.

How to take POMALYST

Your doctor is prescribing POMALYST for you because it has been shown to help people who have previously taken a proteasome inhibitor and REVLIMID® (lenalidomide).

POMALYST is a once-daily pill taken at home or wherever is convenient for you.

POMALYST comes in 4 strengths



Your doctor may prescribe a different dose based on your lab results or how you're feeling.

The suggested starting dose of POMALYST is 4 mg once a day for 21 days out of a 28-day cycle

Your healthcare team will prescribe you a specific dose and dosing schedule for each medicine based on your individual needs.

Sample 28-day dosing cycle

1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

- Take POMALYST every day for 21 days, as shown
- Take dexamethasone 40 mg on days 1, 8, 15, and 22, as shown
- Do not take POMALYST or dexamethasone on days 23-28

Dexamethasone was studied at a 40 mg dosage in patients 75 years of age or younger and 20 mg in patients older than 75 years.

Always follow your physician's instructions with regard to taking POMALYST. If your physician's instructions conflict with this calendar, follow your physician's instructions.

How long should I take POMALYST?

- Take POMALYST exactly as prescribed and follow all the instructions of the POMALYST REMS® program
- Your doctor will decide how long you should take POMALYST, so be sure to follow his or her instructions on treatment schedule and dose



For help with managing your medicine schedule, see the Treatment Calendar section in the Treatment Organizer included in this kit.

Important things to remember when taking POMALYST



Swallow POMALYST capsules whole with water once a day. **Do not open, break, or chew your capsules**



POMALYST should be taken at the same time each day with or without food

Important things to remember when taking POMALYST (continued)



Do not open the POMALYST capsules or handle them any more than needed. If you touch a broken POMALYST capsule or the medicine in the capsule, wash the area of your body with soap and water right away



If you miss a dose of POMALYST and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, skip your missed dose. Do **not** take 2 doses at the same time



POMALYST comes in 4 capsule strengths: 4 mg, 3 mg, 2 mg, and 1 mg. Your doctor will tell you the dose that is right for you



If you take too much POMALYST, call your healthcare provider right away

Important things to remember when taking POMALYST (continued)

What should I tell my healthcare provider (HCP) before taking POMALYST?

- If you smoke cigarettes (POMALYST may not work as well in people who smoke), have any other medical conditions, or are breastfeeding. Do not breastfeed during treatment with POMALYST—it is not known if POMALYST passes into breast milk and can harm the baby.
- **Tell your HCP about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. POMALYST and other medicines may affect each other, causing serious side effects. Talk with your HCP before taking any new medicines.

How should I take POMALYST?

- If you are on hemodialysis, take POMALYST after hemodialysis on hemodialysis days.
- **Do not share POMALYST with other people.** It may cause birth defects and other serious problems.

How should I store POMALYST?

- Store POMALYST at room temperature 68°F to 77°F (20°C to 25°C).
- Return any unused POMALYST to Celgene or to your healthcare provider.

Keep POMALYST and all medicines out of the reach of children

Learn about the possible side effects of POMALYST

Side effects

You may experience side effects while taking POMALYST. These are not all the possible side effects of POMALYST. Tell your healthcare team about any side effect(s) you experience. Your doctor can adjust your dose, which may help reduce your side effects so you can stay on treatment and receive the benefits of POMALYST longer.

To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch

Remember to discuss side effects with your healthcare team, as they can help you manage them.

Serious side effects of POMALYST:

Birth defects
Blood clots
Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia)
Severe liver problems, including liver failure and death
Severe allergic and skin reactions
Dizziness and confusion
Nerve damage
New cancers (malignancies)
Tumor lysis syndrome (TLS)

Common side effects of POMALYST include:

Tiredness
Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia)
Weakness
Constipation
Nausea
Diarrhea
Shortness of breath
Upper respiratory tract infection
Back pain
Fever

Celgene Patient Support[®]

Learn about financial help for POMALYST.

Celgene Patient Support[®]

Pomalyst REMS[®]

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 **Pomalyst**
(pomalidomide) capsules
1 · 2 · 3 · 4 mg

At Celgene, we believe nothing should come between you and your medicine

We know paying for treatment can be difficult. Celgene Patient Support® is here to help you and your loved ones understand the financial help that may be available for POMALYST®.

Financial Help:

Programs that help with the cost of POMALYST® differ by the type of insurance you have. Even if you don't have insurance or enough coverage to pay for your medicine, financial help may be available.



Celgene Patient Assistance Program (PAP)

for qualified patients who are uninsured or underinsured[‡]



Celgene Commercial Co-pay program

for eligible patients with commercial or private insurance (including healthcare exchanges)*



Independent third-party organizations

for patients who are unable to afford their medication (including patients with Medicare, Medicaid, or other government-sponsored insurance)[†]

[‡] Patients must meet specified financial and eligibility requirements to qualify for assistance.

* Other eligibility requirements and restrictions apply. Please see full Terms and Conditions on the Celgene Patient Support® website.

[†] Financial and medical eligibility requirements vary by organization.



Celgene Patient Support®

A single source for access support

Enrollment in Celgene Patient Support® is simple—choose the option that is best for you.



Enroll online at
www.celgenepatientsupport.com



Call us at **1-800-931-8691**,
Monday–Friday 8 AM–8 PM ET
(translation services available)



Email us at patientsupport@celgene.com

Additional helpful resources

Multiple Myeloma Research Foundation (MMRF)

www.themmr.org

203-229-0464

Cancer Hope Network

www.cancerhopenetwork.org

877-HOPENET

Caring Bridge

www.caringbridge.org

651-452-7940

National Comprehensive Cancer Network

www.nccn.org

215-690-0300

Cancer Support Community

www.cancersupportcommunity.org

888-793-9355

The Myeloma Beacon

www.myelomabeacon.com

Myeloma Crowd

www.myelomacrowd.org

International Myeloma Foundation

www.myeloma.org

800-452-CURE

Lotsa Helping Hands

www.lotsahelpinghands.com

Support and guidance for caregivers:

Family Caregiver Alliance

www.caregiver.org

800-445-8106

Well Spouse Association

www.wellspouse.org

800-838-0879

These sites are not owned or managed by Celgene Corporation and Celgene does not take responsibility for their content.

Glossary

Glossary

Anemia

a shortage of red blood cells, which can cause patients to be pale, weak, and tired.

Antibody

specialized cells of the immune system, which can recognize harmful organisms that invade the body and help fight infection.

Bone marrow

a soft spongy tissue in which blood cells are produced that occupies the cavities of bones.

Constipation

a condition defined by difficulty in the passage of hardened feces.

Deep vein thrombosis

a condition marked by the formation of a blood clot in a deep vein that can cause leg pain or swelling.

Dexamethasone

a synthetic steroid medication used in the treatment of many conditions.

Fatigue

weariness or exhaustion.

Immune system

the bodily system that protects the body from foreign substances, cells, and tissues.

Leukopenia

a condition characterized by a shortage of white blood cells, which can make it very hard for the body to fight infections.

M Protein

a type of antibody that does not fight infection and is produced in excess by multiple myeloma patients.

Myeloma cell

a malignant plasma cell in the bone marrow.

Nausea

a feeling of stomach distress with distaste for food and an urge to vomit.

Neutropenia

a condition characterized by abnormally few white blood cells, that causes an increased susceptibility to infection.

Glossary

Overall Survival (OS)

the length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive. In a clinical trial, measuring the overall survival is one way to see how well a new treatment works.

Plasma cells

a type of white blood cell that makes large amounts of a specific antibody.

Progression-Free Survival (PFS)

the length of time during and after the treatment of a disease that a patient lives with the disease, but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works.

Proteasome inhibitor

a drug, used in cancer treatment, which blocks the ability to break down certain cellular proteins and may aid in supporting cancer cell death.

Relapse

the return of a disease or the signs and symptoms of a disease after a period of improvement.

Thalidomide

an immunomodulatory agent used in the treatment of multiple myeloma.

Tumor flare reaction

worsening of a tumor that is often caused by cancer treatment.

Tumor Lysis Syndrome (TLS)

a group of metabolic disturbances that may occur after the initiation of cancer treatment.

Call your healthcare professional for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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