

ASK YOUR DOCTOR IF LENVIMA[®] COULD BE A TREATMENT OPTION

LENVIMA is a prescription medicine that is used by itself as the first treatment for a type of liver cancer called hepatocellular carcinoma (HCC) when it cannot be removed by surgery.



SELECTED SAFETY INFORMATION

LENVIMA may cause serious side effects, including:

- **high blood pressure (hypertension):** High blood pressure is a common side effect of LENVIMA and can be serious. Your blood pressure should be well controlled before you start taking LENVIMA. Your healthcare provider should check your blood pressure regularly during treatment with LENVIMA. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure



Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

Understanding Liver Cancer



Hepatocellular carcinoma, or simply HCC, is the most common type of liver cancer, making up about 80% of primary liver cancers. Primary liver cancer is cancer that begins in the liver. It's completely normal to feel overwhelmed about a liver cancer diagnosis. However, medicines that may help patients with advanced liver cancer are available.

Your treatment plan is based on the stage of the cancer, as well as other health factors and the underlying cause of your liver cancer.

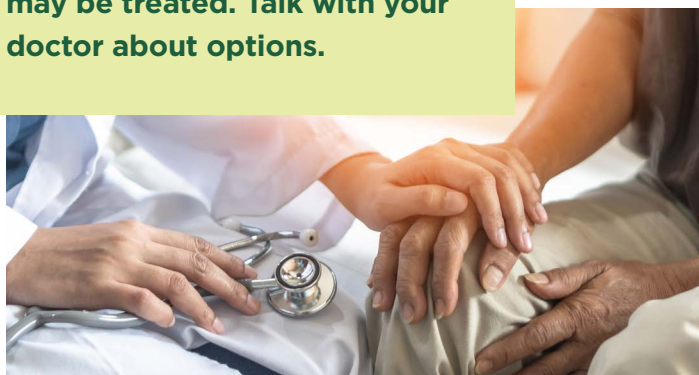
There are 2 general stages of liver cancer—early and advanced.

- **Early stages** of liver cancer may be treated with surgery or transplant and possibly cured
- **Advanced stages** of liver cancer are usually not treatable with surgery

There are some reasons why cancer may not be treatable with surgery:

- Cancer has spread throughout the liver
- The location of tumor(s) in the liver make removal especially difficult
- Patients are not healthy enough to undergo surgery
- Patients refuse surgery

Even advanced liver cancer may be treated. Talk with your doctor about options.



Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

Liver Cancer Risk Factors



Some people have underlying reasons why they are more likely to get a disease than the average person. These are called risk factors.

There are a number of potential risk factors for liver cancer. Some risk factors, such as smoking, diet, and lifestyle choices, can be managed. Others, such as your ethnicity, aren't under your control. The list on the right includes some of the most common risk factors; this list is not comprehensive. Talk with your doctor about the risk factors that may be most relevant to you.

Some risk factors include:



- **Cirrhosis**
- **Diabetes**
- **Non-alcoholic fatty liver disease (NAFLD)**
- **Obesity**
- **Diet**
- **Hepatitis C virus (HCV)**
- **Shared needles**
- **Hepatitis B virus (HBV)**
- **Smoking**
- **Alcohol**
- **Aflatoxin exposure**
- **Ethnicity (Asian American, Pacific Islander, or Hispanic)**

If you'd like more information on these risk factors, please go to OurLenvima.com/risk-english



What Is **LENVIMA?**



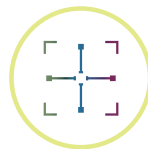
If LENVIMA is prescribed to treat your HCC that cannot be removed by surgery, you may find the following information helpful.

LENVIMA is an FDA-approved, first-treatment prescription medicine used by itself for HCC when it cannot be removed by surgery



LENVIMA may be one of the first medications a doctor prescribes after a diagnosis of HCC when it cannot be removed by surgery.

A targeted therapy



LENVIMA isn't chemotherapy. It is a kind of medicine known as *targeted therapy*. It is called that because it targets certain proteins on cancer cells that cause the cells to grow and multiply. Since healthy cells also contain these proteins, LENVIMA affects some healthy cells, which may cause serious side effects.

Oral capsules that you take at home, once a day, every day

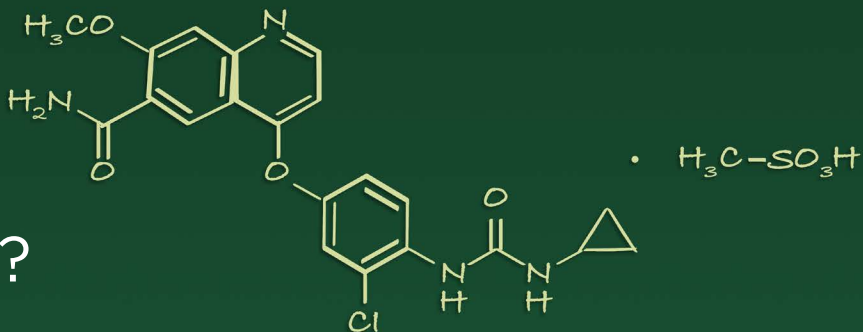


LENVIMA capsules are taken by mouth once a day, every day, at the same time, with or without food. You can even dissolve the capsules in water or juice if you have difficulty swallowing capsules.

The safety and efficacy of LENVIMA have not been established in children.

Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

How Does LENVIMA Work?



It is believed that LENVIMA works by interfering with processes tumors rely upon to grow and live in the body.

There are 2 places in the body where it does this:

Cells

LENVIMA is believed to interfere with the way cells attempt to survive and multiply.



Blood vessels

LENVIMA is also thought to impair some of the activities blood vessels need to grow. Blood vessels support the tumor's survival and growth.



For more information about how LENVIMA works, please go to

[OurLenvima.com/work-english](https://www.ourlenvima.com/work-english)

LENVIMA also affects healthy cells and, as a result, causes serious side effects.



SELECTED SAFETY INFORMATION

LENVIMA may cause serious side effects, including (cont'd):

- **heart problems:** LENVIMA can cause serious heart problems that may lead to death. Call your healthcare provider right away if you get symptoms of heart problems, such as shortness of breath or swelling of your ankles
- **problem with blood clots in your blood vessels (arteries):** Get emergency medical help right away if you get any of the following symptoms: severe chest pain or pressure; pain in your arms, back, neck or jaw; shortness of breath; numbness or weakness on one side of your body; trouble talking; sudden severe headache; sudden vision changes

LENVIMA is proven effective.

LENVIMA was studied in a clinical trial of 954 patients with HCC who were not able to have surgery. The number of patients who were treated with LENVIMA was 478, and the number of patients treated with sorafenib was 476. In this trial, patients were randomly assigned to receive either LENVIMA or sorafenib. The results showed that treatment with LENVIMA was noninferior (not unacceptably worse) in comparison to sorafenib with respect to overall survival.

Patients treated with LENVIMA **lived for a median of 13.6 months**, and patients treated with sorafenib lived for a median of 12.3 months. The median time is halfway between the shortest and longest times that patients lived. Compared to the median time, half of the patients lived longer, and half of the patients lived for a shorter time.



Patients treated with LENVIMA **lived without their cancer getting worse twice as long** as those treated with sorafenib—a median of 7.3 months compared with a median of 3.6 months for sorafenib.

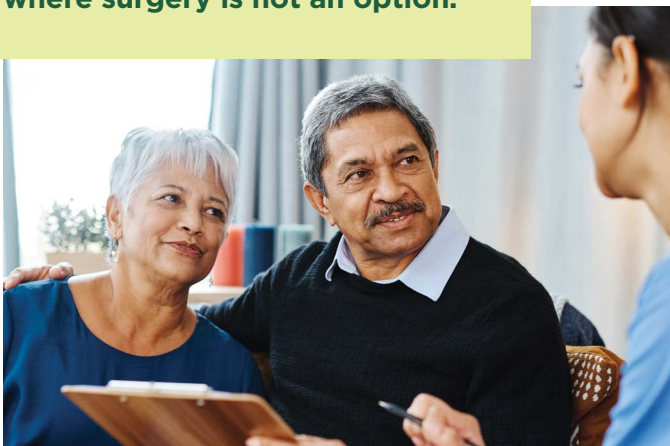


A median is the middle number in a list of numbers arranged from lowest to highest.

Almost 3.5 times as many patients treated with LENVIMA (41%) had their tumors shrink compared with patients treated with sorafenib (12%). Ten patients in the LENVIMA arm (2.1%) vs four patients in the sorafenib arm (0.8%) showed no signs of disease, and 184 patients in the LENVIMA arm (38.5%) vs 55 patients in the sorafenib arm (11.6%) showed some signs of disease.

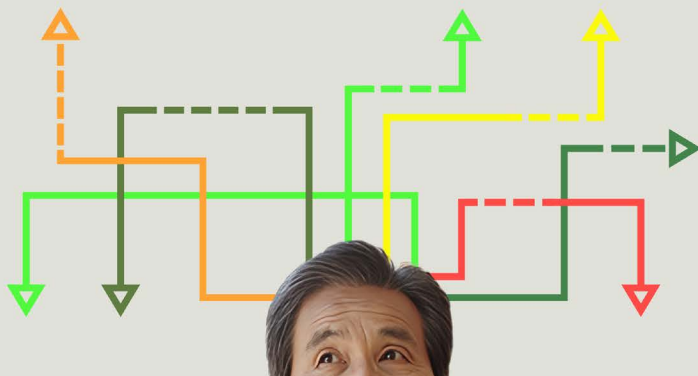


This trial proved that LENVIMA as the first treatment may benefit some patients with HCC where surgery is not an option.



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Before You Take LENVIMA



Talk to your doctor before taking LENVIMA.

If your doctor is having you take LENVIMA, there are some things you need to talk to him/her about first.



Before you take LENVIMA:

- List and describe any current medical conditions
- If you are pregnant, plan to become pregnant, or are able to become pregnant, let your doctor know
- List any herbal supplements, vitamins, and other medicines you're taking
- Especially tell your doctor if you are taking, or have taken, an osteoporosis medicine

Questions to help start a conversation with your doctor.



- How will we know if LENVIMA is the right treatment for me?
- How should I take LENVIMA?
- When should I make my follow-up visits to check on my progress?
- What side effects might I experience from taking LENVIMA?
- When should I talk to you about side effects I may experience?
- How do I know if I can afford LENVIMA?

SELECTED SAFETY INFORMATION

LENVIMA may cause serious side effects, including (cont'd):

- **liver problems:** LENVIMA may cause liver problems that may lead to liver failure and death. Your healthcare provider will check your liver function before and during treatment with LENVIMA. Tell your healthcare provider right away if you develop any of the following symptoms: your skin or the white part of your eyes turns yellow (jaundice); dark “tea-colored” urine; light-colored bowel movements (stools); feeling drowsy, confused, or loss of consciousness

Taking LENVIMA



Capsules not actual size

To get the most out of LENVIMA treatment, it's important to take and store the capsules correctly.

Take LENVIMA capsules exactly as prescribed by your doctor.



- Your doctor will tell you how much LENVIMA to take and when to take it
- It's important that you take this medication exactly how your doctor prescribes
- Your doctor may make changes to the way you take LENVIMA. For example:
 - The number of LENVIMA capsules your doctor prescribes may be reduced during your treatment
 - Your treatment may be stopped for a period of time
 - Your treatment may be stopped completely if you have certain side effects
- Your doctor will determine how many capsules you'll take depending on your body weight. Your starting dose could be two or three 4-mg capsules a day. If you weigh 60 kilograms (132 pounds) and above, your doctor may start you on 3 LENVIMA capsules a day. If you weigh less than 60 kilograms (132 pounds), your doctor may start you on 2 LENVIMA capsules a day

LENVIMA can be taken with or without food.

You can take LENVIMA with or without a meal, so choose a convenient time that works best for you. It should be taken around the same time each day.

For more information about how to take LENVIMA, please go to OurLenvima.com/take-english

How to take LENVIMA by mouth if you cannot swallow whole capsules?



1. Place your daily dose, up to 5 capsules, in a small container or oral syringe (approximately 20 mL capacity)
2. Add 3 mL of water or apple juice to the container or oral syringe
3. Wait 10 minutes for the capsule shell (outer surface) to dissolve completely, then stir or shake the mixture for 3 minutes until capsules are fully dissolved. Do not break or crush the capsules
4. Drink the liquid mixture or use an oral syringe to take directly into the mouth
5. Next, using a second syringe, add an additional 2 mL of liquid to the container or oral syringe (cap the first oral syringe before adding the additional water) then swirl or shake and take the liquid mixture
6. Repeat this step at least one time and until you cannot see any of the LENVIMA mixture left in the container or oral syringe to make sure all of the medicine is taken

If 6 capsules are required for your daily dose, follow the above instructions using 3 capsules at a time.

LENVIMA mixture may be stored in a covered container in the refrigerator at 36°F to 46°F (2°C to 8°C) for a maximum of 24 hours. Throw away the LENVIMA mixture if not used within 24 hours of mixing.

How to give LENVIMA through a feeding tube



LENVIMA should be given in feeding tubes of at least 5 French diameter (polyvinyl chloride or polyurethane tube) and at least 6 French diameter (silicone tube).

1. Place your daily dose, up to 5 capsules, in a syringe (20 mL capacity)
2. Add 3 mL of water to the syringe. Wait 10 minutes for the capsule shell (outer surface) to dissolve completely, then stir or shake the mixture for 3 minutes until capsules are fully dissolved. Do not break or crush the capsules
3. Give the mixture through a feeding tube
4. Next, cap the syringe and remove the plunger. Use a second syringe and add an additional 2 mL of liquid to the syringe. Swirl or shake and give the mixture in the feeding tube. Repeat this step at least one time and until you cannot see any of the LENVIMA mixture left in the syringe to make sure all of the medicine is taken

If 6 capsules are required for your daily dose, follow the above instructions using 3 capsules at a time.

Mixture may be stored in a covered container in the refrigerator at 36°F to 46°F (2°C to 8°C) for a maximum of 24 hours. Throw away the LENVIMA mixture if not used within 24 hours of mixing.

LENVIMA should be taken once a day, at the same time.



Set a reminder to take the same amount of LENVIMA your doctor prescribes once a day at the same time. For example, you may want to take your LENVIMA capsules every morning as soon as you wake up or each evening before you go to sleep. The important thing is that you take it at the same time each day, every day, until your doctor decides to make a change.

What if you miss a dose?

- If it has been no more than 12 hours since you missed your dose of LENVIMA, take it as soon as you remember
- However, if you missed your dose more than 12 hours ago, skip the missed dose. Take your next dose at the regular time

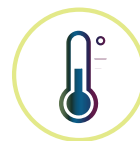
What if you think you've taken too much LENVIMA?



If you think you've taken more LENVIMA capsules than you should have, please:

- Call your doctor right away
- OR
- Go to the nearest hospital emergency room right away

How should you store or keep your LENVIMA?



It's important that you store your LENVIMA (and all medicines) in a safe place away from children. A steady room temperature between 68°F-77°F (20°C-25°C) is best.

Do not use LENVIMA in any way other than how your doctor has prescribed it.

Do not use LENVIMA for any condition other than the one for which it was prescribed. Do not give LENVIMA to other people, even if they have the same symptoms you have, because it could harm them. If you want additional information about LENVIMA, you can ask your doctor or pharmacist.

Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

Managing My Treatment Side Effects

Side effects are possible when you take LENVIMA, and some can be serious. It's important to talk with your doctor about any side effects.

There are steps that can be taken to help manage the side effects of LENVIMA. Your doctor can help you decide what might work best for you. It is important to tell your doctor about any changes in your body, whether you think they are related to your treatment or not.

Serious side effects

The way that LENVIMA is believed to work not only affects cancer cells but can also affect normal cells. This can lead to serious side effects. Call or see your doctor right away if you develop any symptoms or these symptoms get worse:

High blood pressure (hypertension)

A common side effect of LENVIMA that can be serious.

- Your blood pressure should be well controlled before starting LENVIMA
- Your doctor should check your blood pressure regularly during your treatment with LENVIMA. If you develop blood pressure problems, your doctor may prescribe medicine to treat your high blood pressure

Heart problems

LENVIMA can cause serious heart problems that may lead to death. Call your doctor right way if you get symptoms of heart problems such as:

- Shortness of breath
- Swelling of your ankles

Problem with blood clots in your blood vessels (arteries)

Get emergency medical help right away if you get any of the following:

- Severe chest pain or pressure
- Pain in your arms, back, neck, or jaw
- Shortness of breath
- Numbness or weakness on one side of your body
- Trouble talking
- Sudden severe headache
- Sudden vision changes

Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

Liver problems

LENVIMA may cause liver problems that may lead to liver failure and death.

- Your doctor will check your liver function before and during treatment with LENVIMA
- Tell your doctor right away if you develop any of the following symptoms:
 - Your skin or the white part of your eyes turns yellow (jaundice)
 - Dark “tea-colored” urine
 - Light-colored bowel movements (stools)
 - Feeling drowsy, confused, or loss of consciousness

Kidney problems

Kidney failure, which can lead to death, has happened with LENVIMA treatment.

- Your doctor should do regular blood tests to check your kidneys



Increased protein in your urine (proteinuria)

It is a common side effect of LENVIMA and can be serious. Proteinuria is when protein is increased in your urine.

- Your doctor should check your urine for protein before and during your treatment with LENVIMA

Diarrhea

Diarrhea is a common side effect of LENVIMA and can be serious.

- If you get diarrhea, ask your doctor about what medicines you can take to treat your diarrhea
- It is important to drink more water when you get diarrhea
- Tell your doctor or go to the emergency room if you are unable to drink enough liquids and your diarrhea is not able to be controlled

An opening in the wall of your stomach or intestines (perforation), or an abnormal connection between 2 or more body parts (fistula)

- Get emergency medical help right away if you develop severe stomach (abdomen) pain

Changes in the electrical activity of your heart (QT prolongation)

QT prolongation can cause irregular heartbeats that can be life-threatening.

- Your doctor will do blood tests before and during your treatment with LENVIMA to check the levels of potassium, magnesium, and calcium in your blood, and may check the electrical activity of your heart with an electrocardiogram (ECG)



LENVIMA may cause serious side effects, including (cont'd):

Low levels of blood calcium (hypocalcemia)

- Your doctor will check your blood calcium levels during treatment with LENVIMA
- If your calcium levels are low, your doctor may tell you to take a calcium supplement

A condition called reversible posterior leukoencephalopathy syndrome (RPLS)

Call your doctor right away if you get:

- Severe headache
- Seizures
- Weakness
- Confusion
- Blindness or change in vision

Bleeding

LENVIMA may cause serious bleeding problems that may lead to death.

Tell your doctor if you develop any signs or symptoms of bleeding during treatment with LENVIMA, including:

- Severe and persistent nose bleeds
- Vomiting blood
- Red or black (looks like tar) stools
- Blood in your urine
- Coughing up blood or blood clots
- Heavy or new-onset vaginal bleeding

Change in thyroid hormone levels

- Your doctor should check your thyroid hormone levels before starting and every month during treatment with LENVIMA

Wound healing problems

Wound healing problems have happened in some people who take LENVIMA.

- Tell your doctor if you plan to have any surgery before or during treatment with LENVIMA
- You should stop taking LENVIMA at least 1 week before planned surgery
- Your doctor should tell you when you may start taking LENVIMA again after surgery

Severe jawbone problems (also known as osteonecrosis)

Severe jawbone problems have happened in some people who have taken LENVIMA.

- There are certain risk factors that may increase your risk of getting jawbone problems, such as:
 - Taking a bisphosphonate medicine or the medicine denosumab
 - Having dental disease
 - An invasive dental procedure
- Your doctor should examine your mouth before you start and during treatment with LENVIMA. It's important to tell your dentist that you're taking LENVIMA and to practice good mouth care while taking LENVIMA

Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

- Tell your doctor right away:
 - If you have any signs or symptoms of jawbone problems during treatment with LENVIMA, including jaw pain, toothache, or sores on your gums
 - If you plan to have any dental procedures before or during your LENVIMA treatment. You should stop taking LENVIMA at least 1 week before planned dental surgery or invasive dental procedures. Your doctor should tell you when to resume taking LENVIMA. You should avoid having invasive dental procedures, if possible, during treatment with LENVIMA. Stopping your bisphosphonate medicine before an invasive dental procedure may help decrease your risk of getting these jaw problems

Common side effects

The most common side effects of LENVIMA in people treated for liver cancer include **tiredness, decreased appetite, joint and muscle pain, weight loss, stomach (abdomen) pain, rash, redness, itching, or peeling of your skin on your hands and feet, hoarseness, bleeding, decrease in thyroid hormone levels, and nausea.**

LENVIMA may cause fertility problems in males and females and can harm your unborn baby.

Tell your healthcare provider if you are:

- Pregnant or plan to become pregnant. For females who are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with LENVIMA. Use an effective method of birth control (contraception) during treatment with LENVIMA and for 30 days after the last dose of LENVIMA

- Breastfeeding or plan to breastfeed. It is not known if LENVIMA passes into your breast milk. Do not breastfeed during treatment with LENVIMA and for 1 week after the last dose

Your healthcare provider may need to reduce your dose of LENVIMA, or delay or completely stop treatment if you have certain side effects.

These are not all the possible side effects of LENVIMA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Managing common side effect symptoms

There are steps you and your doctor can take to help manage many of the most common symptoms when taking LENVIMA. It's important to contact your doctor right away if you experience any side effects or if any side effects get worse while you're taking LENVIMA.

For more details and some suggestions on managing these side effect symptoms, go to OurLenvima.com/side-english



Help With Affording **LENVIMA**



If you and your doctor decide that LENVIMA is the right medicine for you, Eisai has resources that may help.

There may be assistance available for eligible patients:



- Who are uninsured
- Who don't know if they can afford their capsules
- Who don't know if they can pay their insurance co-pay

Eisai Patient Support

- Understand how your therapy may be covered by your insurance*
- Learn more about out-of-pocket costs for your treatment
- Determine eligibility for assistance if you cannot afford your medication

*Eisai cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record.



Phone: 1-866-61-EISAI (1-866-613-4724)

Fax: 1-855-246-5192

Hours: 8 AM to 8 PM ET,
Monday through Friday

www.LENVIMAREIMBURSEMENT.com

Please note that the link above leads to an English-only website. The phone number provided is staffed with an English-speaking representative. An interpreter who speaks your preferred language can be provided if needed.



Please see Selected Safety Information throughout and on [pages 10-13](#) and full [Prescribing Information](#).

Accessing LENVIMA

Capsules not actual size



You can receive LENVIMA through:

- Certain specialty pharmacies
- Select eligible physician offices or clinics
- Select eligible hospital pharmacies

Specialty Pharmacies

- LENVIMA is available through certain Specialty Pharmacies, which will mail the medication directly to patients.

Please visit

www.LenvimaSpecialtyPharmacy.com

for a complete list of the mail-order Specialty Pharmacies that dispense LENVIMA

Physician office/clinic or hospital pharmacies

- LENVIMA can also be dispensed through eligible physician offices, clinics, or hospital pharmacies. Please contact your preferred distributor for more information, including eligibility requirements

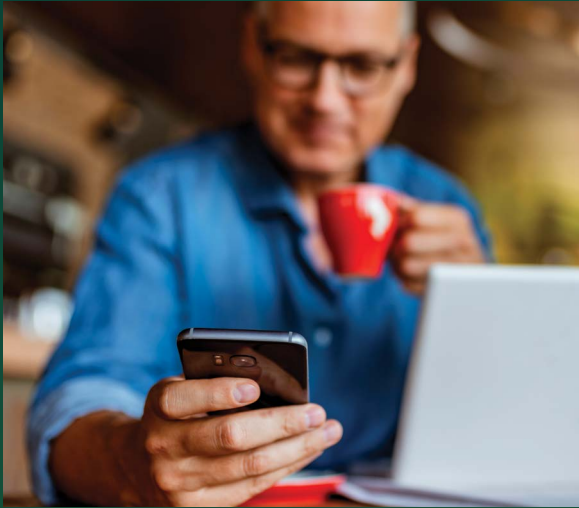


For more information on how to access LENVIMA, please visit

OurLenvima.com/access-english

Please note many specialty pharmacies may also be staffed with an interpreter who speaks your preferred language. Please ask the English-speaking representative for an interpreter.





Learn more at
[OurLenvima.com/english](https://www.ourlenvima.com/english)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ENGLISH

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