For Patients Prescribed ERLEADA®

HELPFUL MEDICARE PART D UPDATES IN 2025

How much and when you pay for your medications covered under your Medicare prescription plan (including Part D and Advantage plans) may change.

WHAT'S CHANGING?

A LOWER ANNUAL COST LIMIT

You will pay no more than **$2,000 per year** for all your generic and brand-name prescriptions covered by your Medicare prescription plan, including ERLEADA®.

MONTHLY BUDGETING OPTION

All Medicare plans will offer a monthly payment plan* that spreads out your costs over the year, with no interest or additional late fees.

*Called the Medicare Prescription Payment Plan.

HOW DO I ENROLL IN THE MEDICARE PRESCRIPTION PAYMENT PLAN?

Simply contact your prescription plan to learn whether you may benefit from the program and sign up. You can enroll any time during the calendar year or during open enrollment from October 15 to December 7. If needed, you can also cancel your enrollment at any time, for any reason. Have questions or need help contacting your prescription plan? Call **1-800-MEDICARE (1-800-633-4227)**.

HOW WILL I PAY FOR MY PRESCRIPTION IF I'M ENROLLED IN THE PAYMENT PLAN?

You will pay nothing for ERLEADA® at the pharmacy. Instead, you will be billed each month by your prescription plan.

Erleada withMe

Once you and your doctor have decided that ERLEADA® is right for you, sign up for **ERLEADA withMe for personalized 1-on-1 support**. You have access to free, dedicated support. Your Care Navigator is here to help guide you to support solutions throughout your treatment journey. Visit **ERLEADAwithMe.com/signup**.

The support and resources provided by ERLEADA withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

What is ERLEADA®?

ERLEADA® (apalutamide) is a prescription medicine used for the treatment of prostate cancer:

- that has spread to other parts of the body and still responds to a medical or surgical treatment that lowers testosterone,

OR

- that has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone.

It is not known if ERLEADA® is safe and effective in females.

It is not known if ERLEADA® is safe and effective in children.

Please see Important Safety Information on page 3.

Please see full Prescribing Information for ERLEADA® also available at ERLEADA.com.

Erleada® (apalutamide) 60 mg tablets 240 mg tablet

WHY ERLEADA® FOR mCSPC

ERLEADA® + ADT was compared with placebo + ADT in a clinical study of 1052 men with mCSPC

- In this study, men received either ERLEADA® 240 mg once daily or placebo. Five hundred and twenty-five men received ERLEADA® + ADT and 527 men received placebo + ADT

Study design: TITAN was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial of patients with mCSPC (N=1052). Patients had newly diagnosed mCSPC or relapsed metastatic disease after an initial diagnosis of localized disease. Patients with visceral (ie, liver or lung) metastases as the only sites of metastases were excluded. Patients were randomized 1:1 to receive ERLEADA® 240 mg orally once daily or placebo orally once daily. All patients in the TITAN trial received a concomitant GnRH analog or had a prior bilateral orchiectomy. The dual primary endpoints were overall survival and rPFS.

ERLEADA® WAS SHOWN TO HELP MEN WITH mCSPC LIVE LONGER

35%
reduction in the risk of death

In a clinical study, ERLEADA® + ADT reduced the risk of death by 35% vs placebo + ADT.*

*Median (middle) follow-up time was 44.0 months. Median data point has not been reached for ERLEADA®. Placebo + ADT median was 52 months. In an earlier analysis from the study, the reduction in the risk of death was 33%.

AT 4 YEARS

65%
of men were alive

In a clinical study, approximately 65% of men taking ERLEADA® + ADT were alive at 4 years vs 52% of men taking placebo + ADT.†

†Median (middle) data point has not been reached for ERLEADA®. Placebo + ADT median was 52 months.

ERLEADA® HELPED MEN ACHIEVE A ZERO PSA LEVEL‡

ZERO PSA LEVEL‡ IN

>2x
as many men vs placebo + ADT

In a clinical study, ERLEADA® + ADT helped more than twice as many men achieve a zero PSA (prostate-specific antigen) level‡ vs placebo + ADT (68% vs 32%).§

‡Zero PSA level = <0.2 ng/mL.
§The relationship between ERLEADA® and PSA is not fully known.

ERLEADA® may cause serious side effects including heart or lung disease, stroke, or severe skin reactions, which can lead to death; falls; fractures; and seizure. Call your doctor right away and stop taking ERLEADA® if you have chest pain, shortness of breath, numbness, weakness, severe rash, peeling, sores, and seizure. Avoid settings where loss of consciousness may cause serious harm. ERLEADA® can cause harm to or loss of an unborn baby. Use birth control during and for three months after ERLEADA®.

Common side effects were joint pain, rash, feeling very tired, high blood pressure, hot flash, diarrhea, and reduced appetite or weight.

mCSPC: Metastatic castration-sensitive prostate cancer.
ADT: Androgen deprivation therapy (ADT) includes medical or surgical treatment that lowers testosterone.
Placebo: Pronounced “pluh-see-bow”: a pill that looks like “real” medicine but contains nothing to affect health.
GnRH: Gonadotropin-releasing hormone.
rPFS: Radiographic progression-free survival.
Median: The middle number in a set of numbers. For 50% of people, this value was larger, and for 50% of people it was smaller.
Prostate-specific antigen (PSA): A protein made by the prostate and found in the blood. Those with prostate cancer may have PSA blood levels that are higher than normal.

Please see Important Safety Information on page 3.
Please see full Prescribing Information for ERLEADA® also available at ERLEADA.com.

Erleada® (apalutamide) 60 mg tablets 240 mg tablet

IMPORTANT SAFETY INFORMATION

Before taking ERLEADA®, tell your healthcare provider about all your medical conditions, including if you:

- have a history of heart disease
- have high blood pressure
- have diabetes
- have abnormal amounts of fat or cholesterol in your blood (dyslipidemia)
- have a history of seizures, brain injury, stroke, or brain tumors
- are pregnant or plan to become pregnant. ERLEADA® can cause harm to your unborn baby and loss of pregnancy (miscarriage).
- have a partner who is pregnant or may become pregnant.
  - Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 3 months after the last dose of ERLEADA®.
  - Males should use a condom during sex with a pregnant female.

  Talk with your healthcare provider if you have questions about birth control.
- are breastfeeding or plan to breastfeed. It is not known if ERLEADA® passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ERLEADA® can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ERLEADA®.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ERLEADA®?

- Take ERLEADA® exactly as your healthcare provider tells you.
- Do not stop taking your prescribed dose of ERLEADA® without talking with your healthcare provider first.
- Take your prescribed dose of ERLEADA® 1 time a day, at the same time each day.
- Take ERLEADA® with or without food.
- Swallow ERLEADA® tablets whole.
- If you miss a dose of ERLEADA®, take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day. You should not take extra tablets to make up the missed dose.
- You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with ERLEADA® unless you have had a surgery to lower the amount of testosterone in your body (surgical castration).
- If you take too much ERLEADA®, call your healthcare provider or go to the nearest hospital emergency room.

What are the possible side effects of ERLEADA®?

ERLEADA® may cause serious side effects including:

- **Heart Disease, Stroke, or Mini-Stroke.** Bleeding in the brain or blockage of the arteries in the heart or in part of the brain have happened in some people during treatment with ERLEADA® and can lead to death. Your healthcare provider will monitor you for signs and symptoms of heart or brain problems during your treatment with ERLEADA®. Call your healthcare provider or get medical help right away if you get:
  - chest pain or discomfort at rest or with activity
  - shortness of breath
  - numbness or weakness of the face, arm, or leg, especially on one side of the body
  - trouble talking or understanding
  - trouble seeing in one or both eyes
  - dizziness, loss of balance or coordination, or trouble walking
- **Fractures and Falls.** ERLEADA® treatment can cause bones and muscles to weaken and may increase your risk for falls and fractures. Falls and fractures have happened in people during treatment with ERLEADA®. Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLEADA®.
- **Seizure.** Treatment with ERLEADA® may increase your risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have a loss of consciousness or seizure. Your healthcare provider will stop ERLEADA® if you have a seizure during treatment.
- **Severe skin reactions.** Treatment with ERLEADA® may cause severe skin reactions that can lead to death or be life-threatening. Stop taking ERLEADA® and tell your healthcare provider or get medical help right away if you develop any of these signs or symptoms of a severe skin reaction:
  - severe rash or rash that continues to get worse
  - fever or flu-like symptoms
  - swollen lymph nodes
  - blisters or sores in the mouth, throat, nose, eyes, or genital area
  - blistering or peeling of the skin
- **Lung problems.** Treatment with ERLEADA® may cause inflammation of the lungs that can lead to death or be life-threatening. Stop taking ERLEADA® and tell your healthcare provider or get medical help right away if you develop any new or worsening symptoms of lung problems, including:
  - shortness of breath
  - cough
  - fever

The most common side effects of ERLEADA® include:

- feeling very tired
- joint pain
- rash. Tell your healthcare provider if you get a rash
- decreased appetite
- fall
- weight loss
- high blood pressure
- hot flash
- diarrhea
- fracture

Your healthcare provider may reduce your dose, temporarily stop, or permanently stop treatment with ERLEADA® if you have certain side effects.

ERLEADA® may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility. **Do not** donate sperm during treatment with ERLEADA® and for 3 months after the last dose of ERLEADA®.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ERLEADA®.

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

Please see full Prescribing Information for ERLEADA® also available at ERLEADA.com.

cp-50508v6

Johnson&Johnson

Erleada® (apalutamide) 60 mg tablets 240 mg tablet