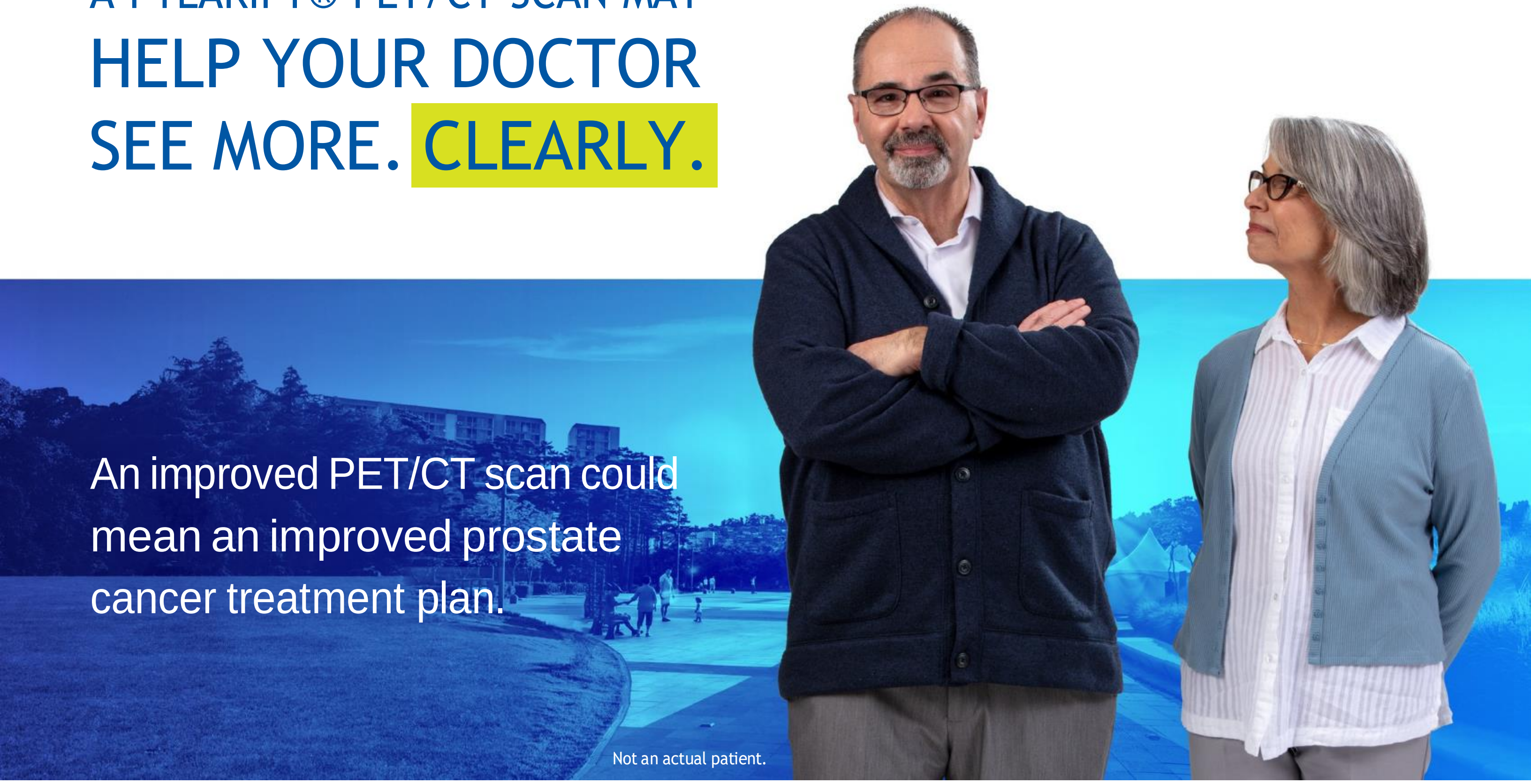
A PYLARIFY® PET/CT SCAN MAY HELP YOUR DOCTOR SEE MORE. CLEARLY.



An improved PET/CT scan could mean an improved prostate cancer treatment plan.

Not an actual patient.

Approved Use

PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent. PYLARIFY is used along with positron emission tomography (PET) imaging for men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum levels of prostate-specific antigen (PSA) level.

PYLARIFY Injection is designed to detect prostate-specific membrane antigen (PSMA) positive lesions when used with PET imaging (scans).

IMPORTANT SAFETY INFORMATION

Radiation exposure:

- PYLARIFY is a radioactive diagnostic agent and adds to your long-term overall amount of radiation exposure, which could lead to an increased risk of cancer. You should stay well hydrated before, during, and after you are given PYLARIFY and urinate frequently to reduce radiation exposure.

CT=computed tomography; PET=positron emission tomography.

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Please see Important Safety Information and the accompanying Prescribing information.

UNDERSTANDING PROSTATE CANCER. CLEARLY.

If you have prostate cancer, you're not alone. In fact, more than 3.1 million American men are currently living with the disease. While this may be an uncertain time, the information in this brochure can help you and your loved ones understand what's ahead to help make informed choices.

Initial prostate cancer diagnosis

As part of your initial diagnosis, your doctor determines your risk group, which helps inform an appropriate treatment plan. There are 5 prostate cancer risk groups to be aware of: **very low, low, intermediate, high,** and **very high**.

Recurrent prostate cancer

Even though initial treatment for prostate cancer can be curative, up to **50%** of patients experience a return of the disease within 10 years, also known as a recurrence.

If you've received treatment for prostate cancer—such as surgery, radiation, or hormone therapy—your doctor will monitor your overall health and run a variety of tests, including one that checks your prostate-specific antigen, or PSA, level. If the test confirms an elevated PSA level, this means the cancer may have returned, or recurred.

Your doctor may schedule an imaging scan to help determine where the prostate cancer is and if it has spread. Imaging scans are important even when PSA levels are still very low.

DEFINITIONS

Initial Diagnosis
This is the first prostate cancer diagnosis you receive.

Recurrent Prostate Cancer
If your prostate cancer came back after you've received treatment such as surgery, radiation, or hormone therapy, you now have recurrent prostate cancer.

Metastatic Prostate Cancer
If cancer spreads beyond the prostate to other parts of your body, it's considered to have metastasized and is now metastatic prostate cancer.

Prostate-Specific Antigen (PSA)
PSA is a protein produced by the prostate cells and mostly found in semen, with a small amount released into the bloodstream. When there is a problem with the prostate—such as prostate cancer—PSA is detected in the blood.

- A PSA test is one of the important steps to help determine an initial diagnosis
- Follow-up PSA tests are performed to determine if a treatment has been successful or if the cancer has come back (recurred)

Prostate-Specific Membrane Antigen (PSMA)
PSMA is a protein found on the surface of most—more than 90%—prostate cancer cells.

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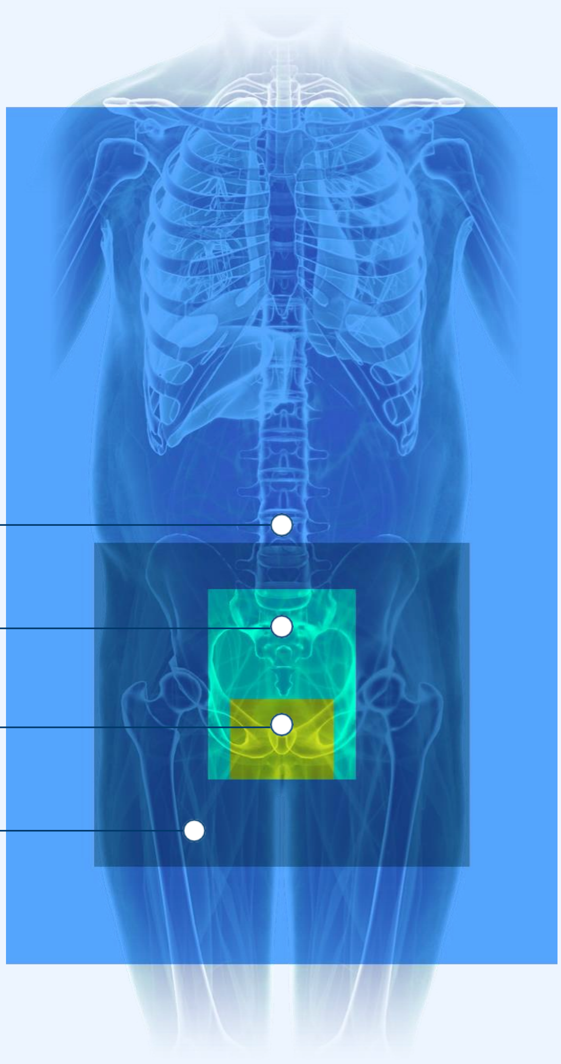
PROSTATE CANCER ASSESSMENT

If your doctor is concerned that the prostate cancer has spread, they may schedule an imaging scan. Your doctor will then assess if the cancer has: remained in the **prostate and pelvic area**, spread into **nearby lymph nodes**, or reached **other parts of the body**. This information will help guide your doctor in the selection of an appropriate treatment.



When detected early, 5-year survival rates for prostate cancer found in the prostate area can be as high as 100%, which is why ongoing screenings are important. Having more information about the different imaging options and steps may help relieve any concerns you have about what's involved.

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DETECTING PROSTATE CANCER. CLEARLY.

Prostate cancer imaging plays a vital role in helping to detect and monitor prostate cancer progression. There are several types of imaging tests, however, not all imaging scans are the same.

A PET scan is often combined with a CT scan for better diagnostic accuracy. Compared to conventional imaging–such as bone, CT, and MRI scans–a PET/CT scan with PYLARIFY® (piflufolastat F 18) injection provides you and your doctor a clearer image of where the prostate cancer is and helps your doctor make more informed treatment choices.

What is a PET scan?

A PET scan is an imaging test that helps doctors look for disease sites in the body. A PET scan uses an imaging agent—like PYLARIFY®—that contains a small amount of radioactive tracer, which targets cancer cells. Once there, the imaging agent lights up, helping the reader of the PET scan find the disease location, usually before tumors appear on other types of imaging scans.

What is PYLARIFY®?

PYLARIFY® is an advanced diagnostic imaging agent used with PET/CT scans to find tumors in the prostate, lymph nodes, bones, and other organs, typically better than other types of imaging scans.

How does PYLARIFY® work?

PYLARIFY® attaches to prostate-specific membrane antigen (PSMA), a protein found on the surface of most—more than 90%—prostate cancer cells. By targeting PSMA, PYLARIFY® can give your doctor a clear image and additional information on the location and the extent of the cancer.

PYLARIFY® helps create clearer images for your doctor

PYLARIFY® uses a radioactive tracer called fluorine-18, or ^{18}F, which helps create a clear and more detailed PET/CT scan image for your doctor. A clearer image also provides improved insights, which can lead to more informed treatment choices.

CT=computed tomography; MRI=magnetic resonance imaging; PET=positron emission tomography.

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Please see Important Safety Information and the accompanying Prescribing information.

PYLARIFY® PET/CT SCAN vs OTHER CONVENTIONAL IMAGING

		CONVENTIONAL IMAGING		
IMAGING TYPE How it works	**PYLARIFY® PET/CT SCAN** Uses imaging agent that contains radioactive tracer. This agent accumulates in prostate cancer tumor(s), enabling earlier and clearer detection than other scans	**CT SCAN** Uses X-rays to create pictures of a cross-sectional view of the body that can not only show shape, size, and location of the organs, but also abnormalities like cancer	**MRI SCAN** Uses strong magnets for a cross-sectional view of the soft tissue of the body, and can also locate cancer. Cannot be used in people with pacemakers or artificial joints	**BONE SCAN** Uses radioactive tracer. This tracer is taken up by abnormal cells, like cancer in the bone that can be detected by scan
DETECTION OF CANCER				
IN BONES	🔵	🔵	🔵	🔵
IN SOFT TISSUE	🔵	🟡	🟡	NA
WHEN IT IS SMALL	🔵*	🟡	🟡	NA
WHEN PSA LEVELS ARE LOW[†]	🔵	🟣	🟣	🟣

🔵 Yes 🟡 Yes, but with some limitations 🟣 No

*Although a PET scan has some limitations when detecting microscopic metastases, it can detect smaller metastases compared to CT or MRI.

[†] PSA <2 ng/mL.

CT=computed tomography; MRI=magnetic resonance imaging; NA=not applicable, can only detect cancer in bones; PET=positron emission tomography; PSA=prostate-specific antigen.

Talk with your doctor

to see if a PET/CT scan with PYLARIFY® (piflufolastat F 18) injection is right for you.

Not an actual patient.

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HOW TO PREP FOR A PET/CT SCAN WITH PYLARIFY®

Drink fluids before and after your scan. Staying properly hydrated and going to the bathroom are important pre- and post-scan

With PYLARIFY®, fasting might not be required. Although fasting before a PYLARIFY® PET/CT scan is not required, your doctor might ask you to

If your doctor thinks a PET/CT scan with PYLARIFY® (piflufolastat F 18) injection is appropriate for you, here are a few things to help you understand the procedure:

Upon arrival

- Your weight and height will be measured and recorded
- An intravenous (IV) catheter line will be placed in your arm or similar vein
- You'll receive an injection of PYLARIFY® 1 hour prior to your PET/CT scan
- It'll take approximately 1 hour for PYLARIFY® to circulate through your bloodstream and into any cancer cells that may be present
- You may be asked to use the restroom after your injection of PYLARIFY® and prior to starting your scan

During the procedure

- After you've received your injection of PYLARIFY®, you'll lie on your back on the scanner bed with your arms raised above your head; a trained PET/CT technologist or nurse will be there to help
- The scanner bed will move slowly into the scanner and the scan will begin. The scan will be painless
- The scan will typically start at your mid-thigh and go all the way up to your head
- The scan could last up to 40 minutes and you may be asked to change body positions

After your scan

- The results will be sent to your doctor
- Be sure to continue to hydrate and go to the bathroom for the first few hours
- Schedule a follow-up appointment with your doctor so together you can see and review the results and discuss a treatment plan

In clinical trials, side effects of PYLARIFY® were minor and rare. The most common side effects were headache (2% of patients), unusual taste (2% of patients), and fatigue (1% of patients). In addition, a hypersensitivity reaction was reported in 1 patient (0.2%) with a history of allergic reactions.

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IMPORTANT SAFETY INFORMATION

How well does PYLARIFY work?

- As with all diagnostic imaging tests such as x-rays, bone scans, and computed tomography (CT) scans, it is possible that the physician (a radiologist or nuclear medicine physician) that reviews your PYLARIFY PET/CT scan could interpret your results incorrectly. This means that a negative PYLARIFY PET/CT scan does not rule out that you have prostate cancer, and a positive PYLARIFY PET/CT scan does not confirm that you have prostate cancer.
- PYLARIFY seems to be affected by the amount (level) of PSA in your blood. As the levels of PSA in your blood go up, a PYLARIFY PET/CT scan is better able to identify prostate cancer.

Hypersensitivity reactions:

- Patients should be monitored for hypersensitivity reactions, especially those with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

Radiation exposure:

- PYLARIFY is a radioactive diagnostic agent and adds to your long-term overall amount of radiation exposure, which could lead to an increased risk of cancer. You should stay well hydrated before, during, and after you are given PYLARIFY and urinate frequently to reduce radiation exposure.

What are the possible side effects of PYLARIFY?

- There were no serious reactions reported in patients who received scans in clinical trials with PYLARIFY, but some patients did report side effects associated with the use of PYLARIFY.
- The most commonly reported adverse reactions are headache, fatigue and unusual taste in the mouth. An allergic reaction to PYLARIFY was reported in one patient with a significant history of allergic reactions.

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

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-888-INFO-FDA (1-888-463-6332).

For more information, please see Full Prescribing information for PYLARIFY.

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TALKING ABOUT PROSTATE CANCER AND PYLARIFY®. CLEARLY.

Ongoing checkups and screenings are important steps you and your doctor can take to monitor prostate cancer. Here are a few questions to help you start or continue the conversation with your doctor:

- Based on the initial diagnosis assessment, or if the prostate cancer has come back (recurred) or spread (metastasized), how can imaging options help determine the extent of the cancer?
- Is a PET/CT scan with PYLARIFY® an option for me?
- Can you talk to me about PET/CT scans and how safe they are?