

New PBS listing for deadly, advanced prostate cancer¹

From 1 June 2023, ERLYAND[®] (apalutamide) will be available on the PBS for the treatment of men living with metastatic hormone sensitive prostate cancer (mHSPC) which affects over 3,000 Aussie men.

- Almost 2 in 3 men with stage four prostate cancer do not survive²: Prostate cancer is now the most diagnosed, and the second most common cause of cancer-related death in Australia.² With 22,000 men diagnosed in 2022², new treatments are vital.
- Once prostate cancer spreads, it is increasingly difficult to survive the condition², therefore the goal is to give patients as much time as possible without impacting their quality of life: Until now, Aussie men have only had access to androgen deprivation therapy (ADT) and chemotherapy for this advanced form of prostate cancer.
- ERLYAND is a non-chemotherapy treatment option and the first of its kind to be listed on the PBS for mHSPC: ERLYAND is taken once per day, with or without food, and is used in combination with androgen deprivation therapy (ADT).^{1,3}

1 JUNE, **2023 (SYDNEY)**: From 1 June, ERLYAND (apalutamide) will be listed on the Pharmaceutical Benefits Scheme (PBS) for metastatic hormone sensitive prostate cancer (mHSPC). This listing provides an additional treatment option for men impacted by metastatic disease, which carries a significantly higher mortality risk than early-stage disease.²

In Australia, five-year relative survival for prostate cancer diagnosed at Stage I is 100%, compared to Stage 4 cancers where it is just 36.4%, demonstrating the vital importance of early detection and of the need for new treatments targeted specifically at metastatic disease.²

Associate Professor Anthony Joshua from St Vincent's Private Hospital Sydney welcomes the PBS listing of ERLYAND as an additional therapeutic option for mHSPC, given the devastation of the disease.

"Metastatic hormone sensitive prostate cancer is a destructive cancer which has substantial impacts on patient survival and overall quality of life.

"ERLYAND is a next-generation oral androgen receptor inhibitor that blocks the action of testosterone in prostate cancer cells and works by preventing androgen from binding to the androgen receptor," Associate Professor Joshua said.

According to Anne Savage, CEO, Prostate Cancer Foundation of Australia, the addition of ERLYAND to the PBS will be met with relief from the patient community.

"Living with metastatic prostate cancer can be incredibly difficult for those with the disease, as well as their loved ones and carers. ERLYAND's listing on the PBS represents an important step forward in providing an alternative treatment option to counter this often aggressive and advanced form of prostate cancer."

"With prostate cancer now being the most prevalent cancer in Australia, the need for continued investment in research to better understand the condition, and for new treatments including ERLYAND to address the condition are crucial."

A rapid rise in prostate specific antigen (PSA) levels signals the imminent spread of cancer. As PSA levels can vary over time, regular PSA testing for those living with mHSPC is recommended.⁴

ERLYAND is an anti-cancer medicine that contains the active substance, apalutamide and belongs to a group of medicines called androgen receptor inhibitors. It is prescribed to individuals with metastatic prostate cancer that still respond to treatments that lower testosterone.⁴



ERLYAND is an oral treatment taken once per day and can be taken at home without the need of attending a hospital or another medical facility. ERLYAND is used in combination with ADT.

According to Urs Voegeli, Managing Director, Janssen Australia and New Zealand, the PBS listing of ERLYAND for mHSPC reflects Janssen's ongoing commitment to those impacted by, and living with prostate cancer.

"Janssen has always been driven by supporting those who may benefit most from ERLYAND, those currently living with prostate cancer. This PBS listing follows the PBS listing of ERLYAND in 2022 for men with non-metastatic castration-resistant prostate cancer, and truly reflects our ongoing commitment to bringing forward treatments for different forms and stages of prostate cancer."

"We extend our warmth and thanks to all those who have contributed to ensuring ERLYAND is now available on the PBS, including the patient and medical communities, as well as the Federal Government."

Prostate cancer accounts for approximately 33% of male cancers diagnosed each year. The risk of being diagnosed with prostate cancer increases with age. For Australian men, the risk of being diagnosed by age 75 is 1 in 7, and by age 85 this increases to 1 in 5.⁵

For more information about prostate cancer and which treatment options are most suitable for you, speak to your doctor.

PBS Information: Authority Required. Refer to PBS schedule for full information.

What is Prostate Cancer?

Prostate cancer occurs when cells in a man's prostate gland grow in an unusual way to form an abnormal growth called a tumour. The prostate, normally a golf ball-sized gland that sits below the bladder, helps produce the fluid in semen. There are different kinds of prostate cancer. While most grow slowly and cause no symptoms for many years, some spread aggressively and cause serious illness and death.⁷

There are two stages of advanced prostate cancer:

- locally advanced prostate cancer where the cancer has spread outside the prostate to nearby parts of the body or glands close to the prostate
- metastatic prostate cancer where the cancer has spread to distant parts of the body.

Advanced prostate cancer symptoms can include:

- frequent urination
- pain while urinating
- blood in the urine or semen
- a weak stream
- pain in the back or pelvis
- weak legs or feet.

More widespread disease often spreads to the bones and causes pain or unexplained weight loss and fatigue.

What is Metastatic Prostate Cancer?

Metastatic prostate cancer means the cancer has spread from the prostate to other parts of the body. It is sometimes called advanced prostate cancer. It most commonly spreads to lymph nodes in other parts of the body or to the bones. It can also spread to other organs such as the lungs. ⁶



There are different treatments for metastatic prostate cancer. These include:⁶

- hormone therapy
- chemotherapy
- steroids
- radiotherapy
- targeted drugs
- radioisotope therapy
- symptom control such as treatment to help with bone pain

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Consumer Medicine Information is available at: <u>http://www.janssen.com.au/erlyand_cmi</u>

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REFERENCES

- 1. Pharmaceutical Benefits Scheme, Apalutamide. Available at:
- https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2022-07/apalutamide-tablet-60-mg-erlyand. Date Accessed: April 2023
- Prostate Cancer Foundation of Australia. Prostate cancer in Australia what do the numbers tell us? Available at: <u>https://www.pcfa.org.au/news-media/news/prostate-cancer-in-australia-what-do-the-numbers-tell-us/</u>. Date Accessed: April 2023
- 3. Janssen. ERLYAND® Product Information. Available at: <u>www.janssen.com.au/erlyand_pi</u>. Date Accessed: April 2023
- Smith M et al. Apalutamide Treatment and Metastasis-free Survival in Prostate Cancer N Engl J Med 2018;378:1408–1418.
- 5. HealthDirect. Prostate Cancer. Available at: <u>https://www.healthdirect.gov.au/prostate-cancer</u>. Date Accessed: April 2023
- 6. Cancer Research UK. What is metastatic prostate cancer? Available at: <u>https://www.cancerresearchuk.org/about-cancer/prostate-cancer/metastatic-cancer/what-is-metastatic-prostate-cancer/metastatic%20prostate%20cancer%20means%20the,organs%20such%20as%20the%20lungs. Date Accessed: April 2023</u>